# THE HEALING ARTS RADIATION PROTECTION GUIDELINES

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# GUIDELINES FOR THE SAFE AND EFFICIENT USE OF X RAYS FOR IMAGING

CHAPTER PAGE

1 INTRODUCTION 1

1.1 The Healing Arts Radiation Protection Act 1

1.2 Principles Of The Ontario X-ray Safety Programme 3

1.3 Purpose And Scope Of The Guidelines 4

1.4 The ALARA Principle In X-ray Diagnosis 7

2 BASIC PRINCIPLES 11

2.1 Radiation effects and risks 11

2.2 Image quality 25

3 TECHNICAL FACTORS INFLUENCING RADIATION DOSE AND IMAGE QUALITY: 33

3.1 Selection of equipment 33

3.2 Choice of technique 34

3.3 X-ray spectrum - waveform, kilovoltage, filtration 34

3.4 Collimation 42

3.5 Anti-scatter device 42

3.6 Image receptor 45

3.7 Image processing 50

3.8 Viewing conditions 50

3.9 Other factors 53

4 INDEXED GUIDE TO THE REGULATIONS 56

5 QUALITY ASSURANCE PROGRAMME 84

5.1 Photographic quality assurance 88

5.2 Patient entrance exposure measurements 99

5.3 Collimation 106

5.4 Half-value layer 109

5.5 Standards of functioning (reproducibility, accuracy, linearity) 117

5.6 Measurement of kilovoltage accuracy 121

5.7 Measurement of mA or mAs linearity 123

5.8 Tests of automatic exposure termination and back up timer 124

5.9 Other timer tests 127

5.10 Measurement of fluoroscopic exposure rates 129

5.11 Measurement of fluoroscopic resolution 135

5.12 Testing the limit timer 137

5.13 Tomographic tests 137

6 ACCEPTANCE TESTING 147

7 MAINTENANCE AND CALIBRATION 165

7.1 Handling of fault 165

7.2 Preventive maintenance 166

7.3 Calibration 167

7.4 Service 170

8 MEDICAL RADIOLOGY GUIDELINES 172

8.1 General guidelines 173

8.2 Guidelines for the prescription of medical x-ray examinations 181

8.3 Performance of diagnostic x-ray examinations 187

8.4 Performance of fluoroscopic examinations 188

8.5 Radiography of the pregnant woman: precautions 190

8.6 Protection of the patient: Final word 196

8.7 Protection of personnel in medical radiology 196

8.8 Quality assurance in medical radiology 199

9 DENTAL GUIDELINES 202

9.1 The ALARA principle 202

9.2 Exposure limits 204

9.3 Selection of equipment and materials 205

9.4 Acceptance testing 206

9.5 Quality assurance programme 213

9.6 Radiation protection methods 224

10 CHIROPRACTIC GUIDELINES 225

10.1 Selection of patients for radiological examination 225

10.2 Selection of equipment 227

10.3 Good radiographic practice 228

10.4 Quality assurance programme 230

11 CHIROPODY (PODIATRY) GUIDELINES 232

11.1 Selection of patients 232

11.2 Radiation risks 232

11.3 Contraindications 233

11.4 Selection of equipment 234

11.5 Protective methods 235

11.6 Radiographic technique 235

11.7 Quality assurance programme 236

11.8 Referral of patients 240

12 REFERENCES 241

APPENDIX - Sample Quality Control Charts

# PREFACE

## Origin of the HARP Act and the HARP Commission

In 1979, public concern regarding exposure to x-rays, compelled the Minister of Health to establish an Advisory Committee on Radiology, with Dr. R.B. Holmes as Chairman. Included among this Committee's recommendations were the elements of the new x-ray safety legislation, Bill 177. This legislation was passed in 1980 and became known as the Healing Arts Radiation Protection (HARP) Act.

Upon the enactment of the HARP Act (Bill 177) the HARP Commission was appointed. One of its first tasks was the development of the Regulations (45/84 and 344/84) intended to promote the safe use of x-rays in the healing arts. The Regulations, promulgated in 1985, take the form of an X-ray Safety Code in which both the standards for equipment performance and the duties of the Radiation Protection Officer are defined.

The Commission, acting upon advice from its Advisory Committees and staff initiated the development of this set of guidelines to accompany the Regulations.

In preparing the Guidelines, great emphasis was placed on the incorporation of detail and the achievement of clarity to ensure that the finished product would be a useful working document.

The preparation of the Guidelines has been coordinated by the Commission's Physics Advisory Committee under the Chairmanship of Dr. M. Cohen and edited by Dr. M. Yaffe with input from the other advisory committees.

The primary objective of the Guidelines is to help the health professional render the risks associated with diagnostic radiation "As Low As Reasonably Achievable".

The Guidelines contain advice and recommendations, but no mandatory requirements.

## The Guidelines

- provide information to the Radiation Protection Officers, assisting them in establishing and maintaining a Quality Assurance Program and in carrying out their other duties, as required by the HARP Act and Regulations;

- assist the Radiation Protection Officer, and indeed the entire staff of an x-ray facility, not just to comply with the letter of the X-ray Safety Code, but to do so in a manner that will help raise the standards of x-ray diagnosis and patient safety throughout Ontario;

- address the relationship between the radiation exposure of the patient and the quality of the image, with optimization of the benefit/risk ratio as the objective;

- address the problem of protecting the patient in x-ray examinations, first from the point of view of prescribing the examination, second during the actual performance of the examination;
- summarize the problems with x-ray safety from the point of view of the operator and other staff participating in the examination;
- indicate what remedial measures can be taken to correct unsatisfactory situations, currently not in compliance with the requirements of the Code;
- define the needs of x-ray users in the area of quality assurance; and
- encourage the users of x-rays for diagnostic purposes, to go beyond the scope of the Act and comply with the ALARA principle.

The Act and Regulations, as legal documents, are necessarily written in concise language and do not provide explanations for each section or requirement. The Guidelines are designed to fill this gap by taking the reader through the Regulations, clause by clause, and providing further information as may be needed to understand the basis of the Regulations and the means of compliance. The Guidelines reflect the legal nature of the document; they also facilitate educational comprehension by the public.

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## ACKNOWLEDGEMENTS

A major revolution in radiological imaging has taken place in the last 15 years, both in terms of the development of new equipment and of exciting new techniques for imaging. As well, in recent years a renewed awareness has emerged of the potential risks of exposure to ionizing radiation and the consequent need to make efficient use of radiation in imaging.

These Guidelines were created by many people; all committed to the idea that radiation in the Healing Arts can be used more safely and effectively.

Significant contributions to the text were made by Dr. Montague Cohen, Dr. Aaron Fenster, Dr. John MacDonald, Dr. Andrew Rainbow and Dr. John Rowlands of the Physics Advisory Committee, Mr. Des Barnes and Mrs. Gail Moffatt of the Radiological Technology Advisory Committee, Dr. David Weston and Dr. Robert Goldberg of the Chiropody Advisory Committee, Dr. George Stirling and Dr. Michael Pharoah of the Dental Advisory Committee and Dr. David Hynes of the Medical Radiology Advisory Committee. Chapter 6 was compiled by Mr. Gordon Mawdsley of the Ontario Cancer Institute and the University of Toronto Radiological Research Labs.

Staff members of the Ontario Ministry of Health X-Ray Inspection Service provided valuable information and constructive criticism based on their extensive experience in the field. In particular, Miss Gail Lowe

contributed much of the material on quality-control techniques for tomography. As well, the document was thoroughly reviewed by all members of the Advisory Committees.

We were also aided greatly by comments from Mr. Joseph Ritchie, Chief of the X-Ray Inspection Service of the Ontario Ministry of Health and by the assistance of coordinators, Ms. Jo Anne Colsen, and Miss Tiina Jarvalt and Mrs. Fareeda Virani who formed a liaison between the HARP Commission and the Advisory Committees. The work of Ms. Evelyn Chatarpaul who painstakingly transcribed the text and performed uncountable modifications to it is greatly appreciated.

It is hoped that these efforts will help make the practice of x-ray imaging in Ontario even safer in the future.

Martin Yaffe, Ph.D.
Editor

# 1 INTRODUCTION

## 1.1 The Healing Arts Radiation Protection Act, 1980

The purpose of the 'HARP' Act is to promote and ensure the safety of all persons involved in the use of x rays in the healing arts which, under the Act, include medical radiology, chiropractic, dentistry and chiropody. The term "person" includes staff, patients and the general public, but the emphasis in the HARP Act falls on the protection of the patient since the safety of the staff and the public is largely covered by other legislation.

"Protection of the patient" implies (apart from mechanical and electrical safety) the reduction of health risks by minimizing the radiation exposure in every x-ray examination. There is, however, another aspect of patient safety of equal importance. A radiograph that fails to provide the required diagnostic information represents both wasted radiation exposure and the possibility of undetected life-threatening disease and is, therefore, a health hazard to the patient. Thus "patient safety" must be interpreted to mean "the provision of a radiological image of good diagnostic quality, consistent with minimum radiation exposure."

The Act provides for the development of Regulations to promote the safe use of x rays in the healing arts. The general legal framework established by the HARP Act and the Regulations under the Act is as follows:

(i) registration and approval of installation of x-ray facilities and equipment;

(ii) definition of the classes of person who may prescribe an x-ray examination of a human subject;

(iii) definition of the classes of person who may operate x-ray equipment for the purpose of irradiating a human;

(iv) appointment by the owner of an x-ray facility of a Radiation Protection Officer (RPO) charged with ensuring that every x-ray machine is maintained in a safe operating condition and with "such other matters" (relating to x-ray safety) "as are prescribed by the Regulations";

(v) provision of legal powers to the Director of X-Ray Safety (appointed by the Minister of Health) to prevent the unsafe use of x rays;

(vi) establishment of the Healing Arts Radiation Protection (HARP) Commission to advise the Minister on matters relating to x-ray health and safety, approve training courses for all personnel involved in the use of x rays, examine such matters as x-ray screening programmes and to develop x-ray safety regulations;

(vii) establishment of Advisory Committees consisting of representatives from each of the healing arts regulated by the Act as well as radiological technologists and medical physicists to advise the Commission.

The Regulations, promulgated in 1985, take the form of an "X-ray Safety Code" in which both the standards for equipment performance and the duties of the Radiation Protection Officer (RPO) are defined. The RPO is responsible for maintaining equipment standards, for keeping appropriate records and for ensuring that a suitable in-house programme of quality assurance is established and carried out. Perhaps most important of all, the RPO (together with the Head of the Department or Clinic, if they are not the same person) is responsible for those aspects of radiation safety that depend on the proper functioning of people rather than machines. These aspects include factors that are not subject to regulation, such as patient positioning, choice of technique and the continuing education of staff at all levels.

These Guidelines are intended to assist the RPO, and indeed the whole staff of an x-ray facility, not just to comply with the letter of the X-ray

Safety Code but to do so in a manner that will help raise the standards of x-ray diagnosis and patient safety throughout Ontario.

## 1.2 Principles Of The Ontario X-ray Safety Programme

During the preparation of the X-ray Safety Code the HARP Commission was guided by the following general principles:

(i) responsibility for x-ray safety, including patient exposure, shall remain firmly "in house": each x-ray facility has to establish and operate (if necessary, with outside assistance) its own safety programme. The Regulations lay down minimum standards for such programmes, depending on the type of facility concerned. The provincial X-ray Inspection Service will continue to inspect x-ray facilities, however, its main role will be to assist and advise x-ray facilities on the attainment of standards and in initiating further improvement.

(ii) 'X-ray safety' has three principal facets: first, x-ray equipment has to satisfy minimum standards of construction and function; these standards are essentially those which apply to new equipment under the provisions of the federal "Radiation Emitting Devices Act", but with some modifications to allow for the presence of equipment which predates the Radiation Emitting Devices Act as well as the inevitable deterioration of performance of equipment with age. Secondly, the maintenance of these standards has to be assured by an in-house programme of quality assurance (QA), which is an important component of the x-ray safety programme of the facility. Thirdly, the QA programme shall include measurements relating to patient entrance exposure both for radiography and fluoroscopy.

(iii) The Regulations specify only a minimum QA/safety programme for each type of facility. Planning and execution of the programme are to be left to the RPO of each facility and these Guidelines are intended to assist the RPO in that task. Even a minimum QA programme can have a significant positive effect on the performance of a facility, including an improvement in the consistency of image quality and a reduction in patient exposure. The operating principle in radiation safety is 'ALARA' - As Low As Reasonably Achievable. No radiation protection officer should be satisfied with a minimum improvement where a large improvement is technically and logistically possible. For this reason "minimum patient exposures" are not specified in the Safety Code. The RPO should strive to reduce all patient exposures to the lowest level consistent with the production of images of good diagnostic quality. Further discussion on ALARA is included in Section 1.4 of this Chapter.

(iv) The "quality" of clinical images is not at present amenable to routine measurement and can be evaluated only by qualified professionals in each discipline. This aspect of x-ray safety is not amenable to regulation. Nevertheless, the importance of optimum image quality cannot be over-emphasized. The HARP Commission, therefore, intends to invite the various professional bodies associated with the Healing Arts to set up a system of peer review to monitor diagnostic image quality and various other aspects of x-ray safety such as the retake rate, the number of views per examination in various procedures, and the use of fluoroscopic procedures including the average exposure time per procedure.

(v) The above measures need to be complemented by a comprehensive system of education and training in x-ray safety, for staff of all types and levels ranging from undergraduate medical students to senior professional workers. The encouragement of educational initiatives, from one-day training courses to extended programmes, is an essential ingredient of the overall programme for x-ray safety in Ontario.

## 1.3 Purpose And Scope Of The Guidelines

These Guidelines are intended to complement the X-ray Safety Code (Regulations) and to provide additional information on many related aspects of x-ray imaging. The Guidelines contain advice and recommendations but not mandatory requirements. Moreover, it should be stressed that any recommended procedure is not necessarily the only satisfactory method of carrying out a given test. On the contrary, the reader is encouraged to develop alternative, improved methods of quality assurance: this is a rapidly changing field and the optimum procedures are bound to change with time.

The needs of the various branches of the health professions with respect to x-ray safety are similar in principle but vary widely in detail, both in nature and extent. The reader is, therefore, advised to consult Table 1-1 which indicates the chapters or sections of these Guidelines that are relevant to each profession.

**Table 1-1 Relevant Chapters In Guidelines For Health Professions**

| | Chapters |
|---|---|
| Chiropractic | 1-7, 10 |
| Dentistry | 1-7, 9 |
| Medical Radiology | 1-8 |
| Chiropody (Podiatry) | 1-7, 11 |

The basic principles of x-ray imaging are common to all the professions covered by the HARP Act: anyone who uses ionizing radiation for diagnostic purposes should understand the nature of the hazards involved and the extent of these risks. A primary objective of the Safety Code, and of these Guidelines, is to help the health professional to render these risks "As Low As Reasonably Achievable". The second primary objective is to help the user to render the diagnostic quality of every image "As High As Reasonably Achievable". These concepts are discussed in Section 1.4.

The complex relationship between image quality and patient dose can be considered in two stages. First, the efficiency of many current practices in x-ray imaging can be considerably improved - i.e. patient exposure can often be reduced - without any significant loss in image quality. Most of the improvements suggested in these Guidelines fall within this category. Beyond a certain stage, however, any further reduction in patient dose can be achieved only at the expense of image quality and, in this region of operation, a compromise is necessary.

Chapter 3, therefore, discusses the technical factors that influence radiation dose and image quality and how these factors contribute to the selection of the appropriate equipment and technique for a given examination.

The "X-ray Safety Code", as a legal document, is necessarily written in concise language and does not provide explanations for each section or requirement. Chapter 4, entitled "Indexed Guide to the Regulations", attempts to fill this gap by taking the reader through the Safety Code, clause by clause, and providing such further information as may be needed to understand the basis of the Regulations and the means of compliance.

Chapter 5 deals with the Quality Assurance programme and describes, for different types of facility, the types of tests which should be carried out. The purpose of each test, the kind of results that are to be expected and the acceptable range of results are explained. The methods described are not necessarily the only satisfactory ways to achieve the desired result. This chapter aims to be reasonable self-sufficient, but not wholly so. The reader will likely want to refer to some of the many excellent recent publications on QA which are listed in the References (Chapter 12).

The X-ray Safety Code requires the radiation protection officer to ensure that appropriate tests are carried out on x-ray equipment, both new and used, as soon as the equipment is installed. These tests are usually described as "Acceptance Tests". Acceptance testing of different types of equipment is discussed in Chapter 6.

Another important aspect of x-ray safety is the proper calibration of equipment so that the operator can be sure that scales and meters mean what they say. This also requires proper maintenance of the equipment. Chapter 7 is devoted to these two subjects, maintenance and calibration.

The first seven chapters of the Guidelines are of general interest and applicability and are relevant to anyone who uses x-rays for diagnosis. Those health professionals who are familiar with the general principles regarding the safe use of x-rays for imaging may wish to begin by reading the Chapter relating to the appropriate health discipline and consult Chapters 2-7 when further information is required.

The final chapters (8-11) relate to specific needs of medical radiology (Chapter 8), dentistry (Chapter 9), chiropractic (Chapter 10) and chiropody (Chapter 11) respectively. In each case the chapter covers the selection of patients for radiological examination, the selection of equipment, good radiographic practice, and quality assurance as it applies to the specialty under discussion.

## 1.4 The ALARA Principle In X-ray Diagnosis

The ALARA principle ("As Low As Reasonably Achievable, social and economic factors being taken into account") was originally enunciated in relation to occupationally-exposed persons (radiation workers). These workers are subject to legal dose limits. ALARA goes further to require that the annual dose actually received by a radiation worker be reduced well below the legal limit, by means of appropriate protective measures, down to the point where the cost of any further reduction in dose would equal or exceed the marginal cost of the detriment thereby averted. In practice this point is extremely difficult to determine, in the absence of precise data on the biological effect of a given dose. There is also great difficulty in weighing dollar costs of safety measures against health risks.

Application of the ALARA principle to patients undergoing x-ray examinations is even more complicated for the following reasons:

1. This type of exposure is not subject to legal annual dose limits.

2. The patient normally receives a benefit, i.e. diagnosis of his disease or injury, in return for any radiation detriment. Indeed, it is a tacit assumption that the benefit far exceeds the detriment.

3. Radiation exposure of patients is subject to variation arising from the choice of equipment and radiographic technique, and these decisions are (within broad limits) legitimate examples of freedom of choice in the healing arts. This freedom is, however, circumscribed by the right of the patient to receive the minimum radiation dose for a given examination.

4. The cost of measures designed to reduce patient exposure is incurred by the owner of the x-ray facility, whereas the cost of any radiation injury is borne by the patient.

5. The cost of reducing patient exposure is not simply related to the reduction achieved. Significant reductions can often be obtained at little or no cost, by more careful selection of patients for x-ray examination, reduction or elimination of x rays required for administrative purposes, reduction in the number of views and in fluoroscopy time, and improvements in radiographic techniques using existing equipment. Further exposure reduction, however, may require significant expenditure.

6. Any reduction in x-ray exposure must not be achieved at the expense of the diagnostic quality of the x-ray image. On the contrary, ALARA (patient exposure) must be balanced against AHARA: As High (image quality) As Reasonably Achievable.

It is virtually impossible to determine the optimum point which balances ALARA (patient exposure), AHARA (image quality) and "social and economic factors" (the cost of any detriment plus the cost of updating or replacing equipment). The following strategy is therefore suggested:

### 1.4.1 Application Of ALARA To X-ray Imaging

1. Every x-ray facility must ensure that its entrance exposures for standard projections are below the legal maximum values stipulated in the X-ray Safety Code. In many cases where the present values are too high, the necessary reductions can be achieved by improving techniques, without purchasing new equipment. Where acceptable images cannot be obtained at exposures below present limits updating of equipment will be necessary.

2. Facilities whose entrance exposures are already at or below the legal maximum values should attempt further reduction by improving techniques, with no (or only minor) changes in equipment. It is important to maintain or even improve image quality during this process, as evaluated by peer review.

3. It is expected that the gradual replacement of older equipment will have the effect of reducing patient exposures further.

4. Finally, the point will be reached where no further reduction in Ontario average exposures can be obtained without compromising image quality. This situation is far down the line and, in any case, may well be influenced by future changes in imaging equipment and techniques.

# 2 BASIC PRINCIPLES

## 2.1 Radiation Effects And Risks

The object of the x-ray examination should be to obtain maximum benefit to the patient for the least possible risk to the patient. Benefit can be related to the information extracted from the examination, the effect on patient management, the change in the individual's health state influenced by the examination or on the overall benefit to society. In order to appreciate the possible radiation risk to the patient, we need to understand how the amounts of radiation occurring during diagnostic x-ray procedures are measured as well as the possible biological effects of such radiation.

### 2.1.1 Quantities and units of radiation measurement

The term exposure is used to describe the amount of radiation in an x-ray beam, not the interaction of the radiation with the patient. Exposure is defined and measured in terms of the ability of x rays to produce ionization in air and is measured in roentgens.

The quantities used to measure ionizing radiation have been traditionally expressed in units defined in the centimetre-gram-second (cgs) system of measurement. More recently the International Commission on Radiation Units (ICRU) has recommended the use of System Internationale (SI) units to describe radiation quantities. In this document definitions will be given in terms of the more familiar older units. For reference, the corresponding S.I. units are defined in Table 2-1.

The term *dose* or *absorbed dose* describes the energy actually absorbed by matter from the radiation field. Absorbed dose is defined in terms of the energy imparted to any irradiated material per unit mass of the material and is measured in *rads* (1 rad = 100 ergs of energy absorbed per gram of material).

A specific absorbed dose does not always result in the same biological effect when different types and energies of radiation are used. As a consequence, the absorbed dose of radiation does not give a true measure of the expected biological effect for all types of radiation. The term *dose equivalent* describes a quantity of radiation which takes into account both the absorbed dose and the biological effectiveness of the radiation under consideration. The unit of dose equivalent is the *rem*, where the dose equivalent in rem equals the absorbed dose in rads multiplied by the quality factor of the radiation. For x rays, the quality factor is taken as 1, such that for diagnostic x-ray procedures the dose in rads and the dose equivalent in rems are numerically equal.

Table 2-1 Quantities And Units Used In Measurement of Radiation

| | | |
|---|---|---|
| Exposure: | 1 coul/kg air | = 3876 roentgens |
| Dose: | 1 gray | = 100 rads |
| Dose Equivalent | 1 sievert | = 100 rems |

For x rays: rems = rads and

sieverts = grays

### 2.1.2 Patient exposure and absorbed dose

The amount of radiation given to, or received by, a patient undergoing a diagnostic x-ray procedure can be expressed in a number of different ways.

The entrance skin exposure (ESE) is a measure of exposure at a location where the skin is presumed to be. The ESE is usually measured using a geometry similar to that used in the actual clinical situation, but without a patient or phantom present. This is also called the "skin exposure without backscatter" or "patient entrance exposure measured in air without backscatter". This measurement is reproducible and is related to skin dose. It is this measurement, taken for a specified radiographic projection and thickness of body part, which must be below the maximum allowable exposures specified in Table 6 of the Regulations.

The skin dose is a measure of the dose received by the patient's skin, where the x-ray beam enters the patient. In conventional radiographic procedures, this usually represents the maximum dose received by any of the patient's tissues. The term is often incorrectly used where what is actually being discussed is entrance skin exposure (E.S.E.).

The organ dose is a measure of the dose received by a specific organ and probably the quantity most closely related to radiation risk. Unfortunately it is also the most difficult quantity to measure. The sizes of radiation fields typically used for diagnostic imaging are smaller than the patient and the x-rays are absorbed non-uniformly as they traverse the patient. Therefore, following the exposure of the patient to an initially uniform beam of x rays, the resulting dose distribution within the patient will be quite complex. Each diagnostic x-ray procedure results in a unique non-uniform distribution of absorbed dose among the various organs of the body. Organ doses can be estimated from measured E.S.E. values using tables of calculated values (Rosenstein,1976, 1985, Kereiakes, 1980).

### 2.1.3 Biological effects of radiation

The detrimental effects of radiation can be classified as somatic, if they become manifest in the exposed individual, or genetic, if they affect his or her descendents. The major somatic effects associated with low doses include radiation-induced cancer and congenital abnormalities, (resulting from exposure to the embryo or fetus).

Somatic radiation effects are further divided into stochastic and non-stochastic effects. A stochastic effect is one where its probability of occurrence in an exposed individual (rather than its severity) increases with increasing radiation dose received. Stochastic effects include cancer induction and genetic mutations.

A non-stochastic effect is one which will occur with certainty following a certain radiation dose and whose severity increases with the dose. Some non-stochastic effects are the formation of cataracts in the lens of the eye, loss of fertility and damage to the blood or blood-forming cells. Non-stochastic effects are observed primarily at high radiation doses which should not normally be encountered in diagnostic radiology. Proper safety procedures in radiology should prevent non-stochastic effects from being observed.

The radiation effects primarily of concern in diagnostic radiology are genetic mutations, somatic effects of cancer induction and damage to the embryo and fetus.

Available information that has been used to quantify the radiation risk resulting from diagnostic x-ray exposure is derived from epidemiological studies, animal studies and theoretical radiobiological studies. The best available information is consistent with several models that predict different risks at the dose levels used in diagnostic radiology. Although there is disagreement among experts as to the precise relationship between dose and effect in humans, it is reasonable and prudent to accept that risk increases with dose and to assume the conservative hypothesis (ie. the most effect for a given dose) that risk increases linearly with dose. This assumption may over-predict risk at low doses.

### 2.1.4 Tissues at risk

Tissues vary in their sensitivities to radiation effects. The risk incurred following radiation depends not only on the dose received and the site receiving the dose, but also on other factors such as the age at the time of irradiation, sex and possibly several genetic factors. As well, it is reasonable to assume that risk is related approximately linearly to the number of cells irradiated. This implies that if, for example, half of the active bone marrow receives a certain dose, the risk of leukaemia induction will be one half of that associated with irradiation of all the bone marrow to the same dose. This is an important reason for carrying out radiological procedures in a way that restricts the radiation beam to the area of interest only.

The most recent analyses of radiation effect data are compiled in the report of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR, 1982), the National Academy of Sciences Biological Effects of Ionizing Radiation (BEIR,1980) and the International Commission on Radiological Protection (ICRP Publication 26, 1977).

Risk values for various tissues, obtained from publications of the ICRP and elsewhere (Mole, 1979), are given in Table 2-2. This indicates, for example, that if an individual receives a dose equivalent of one rem (0.01 sieverts) to the lungs, he/she will incur an additional risk of 20 in a million of fatality from lung cancer. Equivalently, if one million people each receive a lung dose of one rem, 20 additional fatal lung cancers can be expected in the future. As well as giving the estimated likelihood of inducing fatal malignant disease, Table 2-2 gives risk estimates for non-stochastic changes, or substantial genetic defects in live born descendants.

Table 2-2 Risk Of Radiation-Induced Disease For Various Sites

| Site Exposed | Risk per rem [a] |
|---|---|
| **Cancer Mortality** [b] | |
| A. breast | 25 in a million [c] |
| B. lungs | 20 in a million |
| C. active bone marrow (leukemia) | 20 in a million |
| D. bone | 5 in a million |
| E. thyroid | 5 in a million |
| F. whole body exposure | 125 in a million |
| **Other Disease** | |
| G. Risk of serious hereditary ill health in the first 2 generations following irradiation of either parent | 100 in a million |
| H. Combined risk of cancer plus serious malformations following irradiation of the embryo and fetus | 1000 in a million |

[a] Risk averaged over both sexes and all ages

[b] Cancer induction rates are approximately twice the mortality values given here

[c] Risk in males negligible, in females 50 per million per rem.

### 2.1.5 Risk of diagnostic x-ray procedures

The risk to the patient resulting from radiation exposure is likely to represent only a small contribution to the total risk of the procedure from all causes. For example, for the IVP examination, mortality due to reaction to the contrast medium is reported as 11 per million examinations (Hobbs, 1981), cardiac or respiratory arrests as 170 per million examinations; and severe hypotension in 500 per million examinations. Intravenous cholangiography has an even higher incidence of complication, death being recorded as 200 per million examinations (Teplick,1981).

### 2.1.5.1 Calculation of radiation risk

It is assumed that the relative genetic risk will be proportional to gonad dose over the dose range typically encountered in diagnostic x-ray procedures. Gonad doses for various diagnostic procedures can be readily calculated from measurements of skin entrance exposure and a knowledge of beam quality (HVL) value using published tables (Rosenstein,1976). An example of such data is given in Table 2-3. The genetic risk to the offspring of an exposed individual would be calculated by multiplying the gonad dose by the risk factor from row G of Table 2-2. Gonad doses for various diagnostic x-ray procedures, together with knowledge of the age distribution of affected patients can give information on the genetically significant dose to the population.

In a similar way, the risk of radiation exposure to the embryo and fetus can be determined from the product of the fetal or embryonic dose and the appropriate risk factor as given in row H of Table 2-2. The consideration of genetic and fetal or embryonic risk from diagnostic procedures should take into account that the "natural" level of serious abnormalities is between 3 and 5% of all live births (i.e. between 30,000 and 50,000 per million births).

### Table 2-3 Organ Dose (mrad) For 1000mR Entrance Skin Exposure (free-in-air)

Conditions. SID - 102 cm (40")
Film Size = Field Size - see each projection
Entrance Exposure (free-in-air) - 1000 mR

PROJECTION - PA Cholecystography
25.4 cm x 30.5 cm (10" x 12")

| Beam Quality | Dose, mrad/ 1000 mR | | | | | |
|---|---|---|---|---|---|---|
| HVL (mm Al) | 1.5 | 2.0 | 2.5 | 3.0 | 3.5 | 4.0 |
| Testes | ** | ** | ** | ** | ** | ** |
| Ovaries | 0.8 | 1.6 | 3.0 | 4.8 | 7.1 | 10 |
| Thyroid | 0.1 | 0.3 | 0.5 | 0.8 | 1.2 | 1.6 |
| Active Bone Marrow | 17 | 24 | 33 | 44 | 56 | 70 |
| Embryo (Uterus) | 0.7 | 1.5 | 2.6 | 4.1 | 6.0 | 8.3 |

PROJECTION - AP Upper GI
35.6 cm x 43.2 cm (14" x 17")

| Beam Quality | Dose, mrad/ 1000 mR | | | | | |
|---|---|---|---|---|---|---|
| HVL (mm A1) | 1.5 | 2.0 | 2.5 | 3.0 | 3.5 | 4.0 |
| Testes | 0.07 | 0.2 | 0.3 | 0.5 | 0.8 | 1.1 |
| Ovaries | 13 | 22 | 32 | 44 | 56 | 70 |
| Thyroid | 0.3 | 0.8 | 1.4 | 2.2 | 3.2 | 4.4 |
| Active Bone Marrow | 12 | 18 | 26 | 35 | 47 | 61 |
| Embryo (Uterus) | 9.5 | 16 | 25 | 34 | 45 | 56 |

** < 0.1 mrad
From Rosenstein, 1976

In order to calculate the somatic risk for a given diagnostic x-ray procedure, it is necessary to know the absorbed dose in each susceptible organ together with the risk per rem associated with irradiation of that organ. First the dose is estimated by multiplying the entrance skin exposure in roentgens for a radiological view by the appropriate entry in a table like Table 2-3. The risk for each organ would then be obtained by multiplying the dose to the organ by a risk factor for that organ such as those in rows A-F of Table 2-2. The total somatic risk to the patient would then be the sum of the risks for each of the individual organs. This and somewhat similar procedures have been used to determine the somatic risk from various diagnostic x-ray procedures (Gregg 1977, Laws, 1978). For comparison, general cancer mortality statistics for Canada in 1982 show rates of 1937 and 1507 per million for males and females respectively.

### 2.1.6 Somatic dose index

Another means of estimating radiation risk is via the somatic dose index. This takes into account the fact that different organs have different sensitivities to radiation damage, and provides a method of combining the various doses to several organs in order to assess the overall impact from a particular diagnostic procedure. Conceptually, the somatic dose index is the uniform whole body dose that has the same somatic detriment in terms of cancer mortality as the non-uniform exposure resulting from the diagnostic x-ray procedure. The somatic dose index for various diagnostic x-ray procedures have been tabulated per roentgen of skin entrance exposure for different beam qualities (HVL) (Laws, 1978). It is thus possible to calculate the somatic dose index (or whole body dose equivalent) for any procedure provided that the skin entrance exposure and the HVL are known and that the field size, direction and location of the fields are the same as those used in the tables. For multi-image examinations the somatic dose index is calculated by adding the values for all images in the examination.

The somatic dose index for men and women is different due to the slightly different rates of leukaemia risk per rem for the two sexes and the importance of breast cancer in women. Typical values of the somatic dose index for commonly-performed examinations (excluding fluoroscopy) are given in Table 2-4. The inclusion of fluoroscopy would result in a considerable increase in the somatic dose index for the procedure.

The risk to an individual from a procedure can be obtained by multiplying the somatic dose index by the risk of fatal cancers per rem of whole body irradiation (row F of Table 2-2). The relative risk of the various diagnostic procedures to the population is obtained by multiplying the risk of the procedure by the number of procedures carried out.

According to the ICRP, the risk of fatal cancers from uniform whole body radiation is:

| | |
|---|---|
| Men | 100 per million fatal cancers per 1000 mrem |
| Women | 150 per million fatal cancers per 1000 mrem |

The difference being due to breast cancer in irradiated women.

Table 2-4 Somatic Dose Index For Common Radiological Examinations*

| Examination Carried Out Under Typical Conditions | Somatic Dose Index (mrem) Male | Female |
|---|---|---|
| Chest | 8 | 11 |
| Mammography | – | 450 |
| Skull | 45 | 35 |
| Cervical Spine | 52 | 49 |
| Ribs | 135 | 265 |
| Shoulder (1) | 19 | 46 |
| Thoracic spine | 155 | 315 |
| Cholecystogram | 90 | 46 |
| Lumbar spine | 175 | 91 |
| Upper G.I. | 231 | 138 |
| KUB | 57 | 29 |
| Barium enema | 260 | 132 |
| Lumbosacral spine | 231 | 119 |
| IVP | 158 | 82 |
| Pelvis | 36 | 19 |
| Hip (1) | 21 | 11 |
| Full spine (chiropractic) | 98 | 167 |

* Excluding fluoroscopy (from Laws (1978))

The risk of cancer mortality from diagnostic x-ray procedures thus lies in the range of about 1 in a million for a chest examination to about 45 in a million for mammography and perhaps 100 in a million or more for some fluoroscopy procedures. For reference, the estimated risk from natural background radiation is 10 fatal cancers per million people per year.

Some mortality risks of 1 in a million have been summarized by Sir Edward Pochin, (Pochin, 1978) and are as follows:

400 miles by airplane travel
60 miles by car
smoking 3/4 of a cigarette
1.5 minutes rock climbing
1.5 weeks of typical (UK) factory work
20 minutes of being a man aged 60

### 2.1.7 Variations in exposures received by patients

Dr. K.W. Taylor (Taylor, 1979) and colleagues at the University of Toronto, the Ontario Ministry of Health and others (NCDRH, 1984; Cohen, 1985; Carrier, 1981; Rainbow, 1977; Aldrich, 1981) have shown that there can be wide variations in the amount of radiation to which the patient is exposed during a particular type of radiological examination. Let us assume that the average exposure given is reasonable for each type of examination. Table 2-5 shows the variation above and below this average as found in Ontario hospitals and clinics.

Table 2-5 Variations In X-Ray Exposure To Patients For Common Views

| | Ontario Average Exposure (mr) | Maximum Exposure (mr) | Minimum Exposure (mr) |
|---|---|---|---|
| Abdomen | 309 | 1913 | 5 |
| Chest | 13.8 | 146 | .4 |
| Lat. Lumb. Spine | 1300 | 5504 | 57 |
| A.P. Thorac. Spine | 263 | 2178 | 7.1 |

Although one cannot define the precise radiation exposure that should be used for each examination, it is clear that such large variations are not necessary. Those installations using the highest exposures can certainly alter the techniques or equipment used to reduce radiation exposures and risks considerably. At the same time, and equally important, those installations using the lowest radiation exposures may well be doing so at the expense of an adequate diagnostic image. It would be in the best interest of those receiving x-ray examinations if the range of exposures among the various installations were decreased while at the same time it were ensured that all images were of acceptable quality.

### 2.1.8 Approach to the safe use of x rays for imaging

The primary aim of radiation protection for the patient is to limit the risks of the stochastic effects to a level as low as is compatible with obtaining the necessary diagnostic information required for the particular patient.

Quantitative analysis has shown that a reduction in patient entrance exposure values would be expected to result in a reduction of organ doses received during diagnostic radiology and therefore, result in a reduced radiation risk to the patient (Laws,1980). However, there are several reasons why the implementation and enforcement of maximum skin entrance exposure values alone, would not be sufficient to resolve the problem completely.

First, it is important to understand that the production of a radiological image involves the complex interplay of several technical factors; among them the x-ray spectrum, the performance of the anti-scatter device and the energy absorption, spatial resolution, sensitivity and contrast properties of the image receptor. It is possible to produce images which vary widely both in their technical quality and in the amount of radiation used to produce them. Assuming that there is good justification for performing the examination in the first place, and that the patient will benefit from the procedure, mere restriction of radiation levels without concern for image quality could do more harm than good. The image quality must always be taken into consideration along with radiation exposure. If, under special conditions, it is necessary to use more radiation to obtain the necessary information from the exam then that should be the prerogative of the professional involved. The complexity of the image-forming process, and its dependence on radiation levels and the variety of reasons for performing examinations preclude the strict regulation of image quality.

At the same time, there are well-established basic principles for producing high quality images and for minimizing radiation dose. When the required level of image quality is defined (a difficult and generally non-quantitative task) then the exposure technique and equipment can be selected to obtain the images at the lowest possible exposure.

## 2.2 Image Quality

An image produced by any imaging system is useful only if it is of sufficient quality to allow visualization of the necessary anatomical detail. The visibility of detail is affected principally by three variables: 1) unsharpness; 2) contrast; and 3) noise.

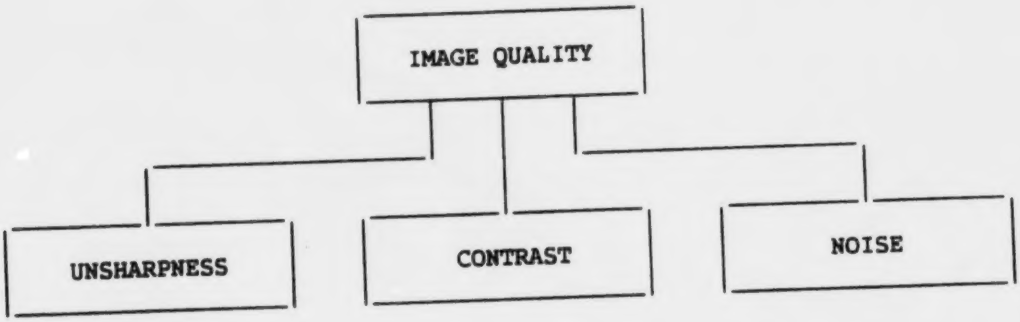

Figure 2-1 Components Of Image Quality

### 2.2.1 Image unsharpness

Image unsharpness refers to the blurring in the image of sharp borders of the object. This is caused primarily by three factors: 1) geometry; 2) image receptor; and 3) motion.

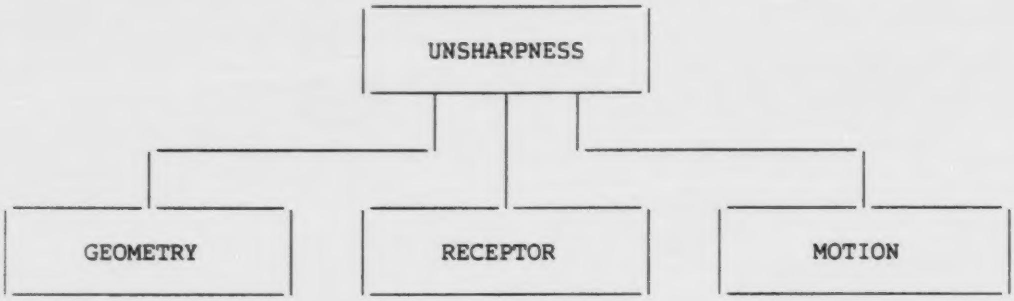

Figure 2-2 Factors Affecting Image Unsharpness

#### 2.2.1.1 Geometric unsharpness

Some of the more important causes of blurring in the image are determined by the geometrical constraints under which the image is formed. In general, these conditions include the size of the radiation source and the distances which define the imaging geometry. If the source of radiation were a "point" focal spot, then the borders of structures in the patient would be projected undistorted onto the x-ray detector. When the size of the focal spot is increased, the image of the sharp borders becomes blurred. The distance over which the borders blur increases with the magnification and the size of the focal spot. This increase in geometrical unsharpness is the principal factor limiting the amount of useful magnification.

#### 2.2.1.2 Receptor unsharpness

The ability of the image receptor to record the information impinging on it also influences the overall unsharpness in the image. The primary cause of receptor unsharpness in film/screen images is lateral diffusion or spread of light between its point of origin in the intensifying screen and the film. The amount of spread of light increases with the thickness of the screen. A secondary cause for unsharpness is the lack of intimate contact between the screen and film.

Similarly, in fluoroscopy unsharpness results from the spread of light and electrons at both the input and output phosphors of the image intensifier. The use of cesium iodide as an input phosphor material has significantly improved the sharpness of image intensifiers since the cesium iodide crystals act as "light pipes" restricting the spread of the light. As well, much work has been done to develop output phosphor designs which minimize unsharpness.

Another important factor influencing the unsharpness of the fluoroscopic image is the focusing of imaging components, notably the electronic focus of the image intensifier, the optics which couple the image intensifier to the television and/or photofluorographic camera and the focusing of these cameras themselves. The focus of these components, especially the electrical adjustments does tend to drift in time and must be adjusted periodically for optimum imaging performance.

#### 2.2.1.3 Motion

All imaging systems are degraded by patient, x-ray tube or detector motion during the time the image is formed. In general, the degree of motion unsharpness can be reduced by reducing the exposure time.

### 2.2.2. Image contrast

Contrast describes the difference in optical density between two points in an image. In general, the greater the contrast, the greater is our ability to detect the difference between two structures. Three major variables affecting image contrast are: a) tissue contrast; b) imaging technique; and c) receptor contrast.

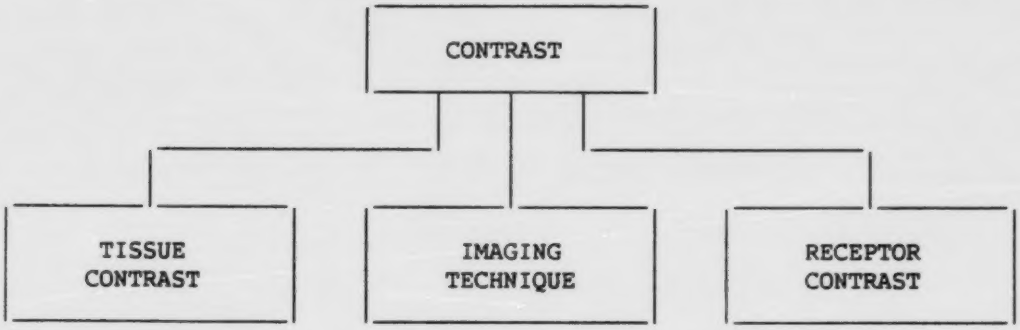

Figure 2-3 Factors Affecting Image Contrast

### 2.2.2.1 Tissue contrast

The patient's composition and geometry affects the distribution of radiation reaching the image receptor. The primary factors affecting the transmission of x rays through the patient are: physical density and atomic number of the tissues and the thickness of the part that is imaged. The atomic number plays a very important role in determining the contrast, since the higher the atomic number of the tissue the greater is the fraction of the total interaction that is by photoelectric effect and hence the greater is the contrast.

The object contrast can be artificially changed by introducing into the patient contrast agents which have a different physical density (air) and/or atomic number (barium and iodine-containing compounds) from the surrounding regions.

### 2.2.2.2 Technique selection

The selection of x-ray tube voltage can greatly alter the image contrast. By selecting a lower tube voltage, more of the x-ray interactions in the patient will be by the photoelectric effect and therefore differences in atomic number will be more apparent. On the other hand, if these differences (bone-tissue) interfere with the visualization of soft tissue structures, then selection of higher voltages will reduce this interference (eg. chest radiography).

### 2.2.2.3 Receptor contrast

The image contrast is not only affected by the pattern of radiation reaching the image receptor, but also by the characteristics of the receptor in transforming this pattern into a visible image. The most important receptor factor affecting radiographic contrast is the characteristic or H-D curve of the processed film. Films exhibiting a higher average gradient will have a greater receptor contrast. H-D curves also exhibit "toe and shoulder" regions in which the curve is nearly flat and hence the contrast is low.

### 2.2.3 Image noise

Image noise is a term used to describe fluctuation in the image not related to the object. The major contributors to image noise are: 1) quantum mottle; 2) receptor noise; and 3) scatter.

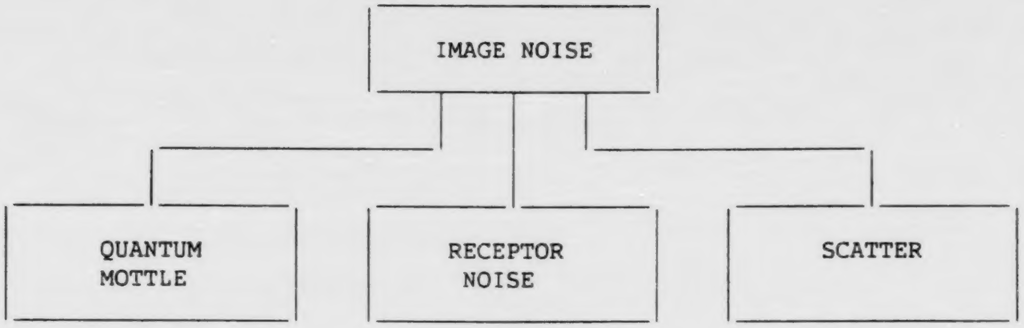

Figure 2-4 Factors Affecting Image Noise

### 2.2.3.1 Quantum mottle

Quantum mottle results from the recording of a finite number of x-ray photons to form the image. This source of noise is governed by the Poisson probability law which is based on the fact that the number of x-rays per unit area of the x-ray beam fluctuates continually at every location in the beam. Thus if one records an image the number of x-ray photons at any two locations will likely be different. This results in an image whose appearance is sometimes described as "salt and pepper". This source of noise is usually the dominant factor of image noise. To reduce its effect, the number of recorded x-ray photons must be increased. This can be accomplished by reducing the film speed and increasing the patient exposure.

### 2.2.3.2 Receptor noise

Image noise may also be affected by the receptor used to record the image. In film/screen imaging both the film and the screen can be sources of receptor noise.

The films contain a wide variety of granules in the emulsion. The development of these granules gives the image a grainy appearance, an effect described as "film graininess" or "film noise". The screen noise or mottle is caused primarily by fluctuations of the sizes of flashes of light in the active layer of the screen. The fluctuation of the light flashes reflects irregularities in the screen phosphor. With modern intensifying screens, screen mottle is not an important contributor to image noise, however, film granularity due to use of an overly sensitive type of film can impair image quality significantly.

#### 2.2.3.3 Scatter

Scattered radiation interferes severely with the visualization of anatomic detail. Not only does scatter decrease radiographic contrast but it also adds quantum noise without adding any information. The proportion of scatter and radiation reaching the image receptor increases with patient thickness, field size and kVp. Scatter can be minimized by collimation, use of grids and air gaps.

### 2.2.4 Measurement of image quality

A number of test phantoms have been designed to assess image quality both objectively and subjectively.

#### A. Objective tests: Resolution

The resolution of the imaging system is determined by the use of parallel bars of various widths and varying degrees of separation. The separation is designated in terms of number of line pairs (a line and the space between the lines) per millimeter. The test object is constructed of thin lead foil bars embedded in a thin layer of plastic. Using this system, the resolution is described as the maximum number of lines per millimeter visible in the image.

A more sophisticated method of measuring resolution, often used by equipment manufacturers is the modulation transfer function or MTF. For information on this procedure refer to Doi, 1982; Rossman, 1969.

## B. Subjective Phantoms

Since patients cannot be irradiated as a check of image quality, test phantoms of various types designed to simulate the patient are used. The phantom's x-ray characteristics should approximate those of the patient. These phantoms are generally designed for particular procedures or functions. In use, they are imaged under the same conditions as the patient and the resulting image is evaluated subjectively.

One type of phantom consists of human bones embedded in plastic. The plastic is tissue equivalent and has the same absorption and scatter characteristics as human tissue.

Information on available phantoms can be obtained from suppliers of x-ray equipment and film and from companies specializing in the supply of quality control equipment.

# 3 TECHNICAL FACTORS INFLUENCING RADIATION DOSE AND IMAGE QUALITY:

## 3.1 Selection Of Equipment

This is one of the most important aspects in the development of a safe and efficient imaging facility. Major improvements have occurred in imaging technology in the last few years and these can be used to great advantage, both in reducing patient doses and in improving image quality. Because the lifetime of some components of x-ray equipment can be ten to fifteen years, it is essential to make knowledgeable decisions when there is an opportunity to select equipment. Once the equipment is in place a certain amount of further optimization of technique can be done, however, it is often impossible to correct completely a problem that is the result of improper choice of equipment.

In a medical radiology facility, it is suggested that the committee responsible for selection of equipment include: a radiologist, a medical physicist, the chief technologist or technical administrator and a technologist who will be responsible for the actual operation of the equipment. The latter is especially important since this person will be familiar with the detailed requirements of the examinations and may appreciate mechanical or human engineering aspects of the equipment which might be overlooked by others.

## 3.2 Choice Of Technique

Once equipment is selected, it is important that it be used in such a manner that the best images are produced at the lowest dose to the patient and personnel. The major technique factors which influence dose and image quality are: the choice of kilovoltage, the type and amount of added filtration to the x-ray beam and the collimation or confinement of the primary x-ray beam. As well, the importance of optimal film processing technique (time, temperature, chemistry, etc.) cannot be overestimated. For fluoroscopic equipment, the above factors as well as the adjustment of the operating variables of the imaging chain have a critical effect on dose and image quality.

In the following sections both the selection of equipment and the optimal use of the equipment will be discussed.

## 3.3 X-Ray Spectrum - Waveform, Kilovoltage, Filtration

### 3.3.1 X-Ray generator

Generators are characterized by such parameters as type of power supply (waveform), type of exposure control and power rating. The choice of a generator will depend on such factors as workload, special or general purpose use, and the needs of specific types of examinations.

### 3.3.2 Choice of waveform

The type of power supplies: single phase, three phase, capacitor discharge or battery-operated will depend on the requirements of the examinations to be performed with the equipment. Of importance is the fact that the effective kilovoltage becomes closer to the selected kVp as the power supply waveform becomes closer to direct current. For example, for a nominal 100 kVp supply, the effective kVp for a three phase twelve pulse generator is 98.9, for a three phase six pulse unit 95.6 but for a single phase full wave unit the effective kVp is only 70.7. This means that both the x-ray output per mAs and the penetrating power of the beam will be higher in the former units than in the latter and that, for the same kVp, patient dose will be lower and exposure times can be shorter. For the same effective output, a generator with a lower peak kilowatt rating can be selected when three phase or high frequency equipment is used.

Also of importance is the minimum time in which the generator can produce x-ray exposures. For full-wave rectified single phase generators, the shortest possible exposure time is 1/120 second or 8.3 milliseconds. This is adequate for much of general radiography. On the other hand, short pulses are often required in angiographic and high-speed photospot camera applications where three phase generators or high frequency generators can produce exposures of 1 millisecond or less.

In choosing a generator other important factors which must be considered are the reliability of the generator and the availability and quality of service as well as cost. Information on reliability and quality of service can usually be obtained by consulting one's colleagues in other x-ray facilities who have experience with various companies. Some of the questions to be asked are: What is the record for breakdowns? What is the response time for a service call? Is the machine repaired in a reasonable length of time? What is the cost for service? Is there general satisfaction with the handling of complaints? Also of importance is a commitment by the supplier to stocking the most commonly-required replacement parts within a reasonable distance of the x-ray facility.

### 3.3.3 Kilovoltage

The ability of the x-ray beam to pass through tissues depends on its "quality", ie on the spectrum of x-ray energies. This depends on the anode material of the x-ray tube, the waveform of the x-ray generator, the kilovoltage and the total filtration of the beam. Once the equipment is in place, kilovoltage is the most easily varied of these factors and, therefore, is the one most commonly varied to control the penetrating power of the x-ray beam. In general, for a given resultant film density or fluoroscopic image brightness, an increase in kilovoltage results in a lower exposure to the patient being required. For example, for a 20 cm thick water phantom the entrance exposure required to obtain an acceptable film density might decrease with kilovoltage as shown in Figure (3-1). This is accompanied by a decrease in the absorbed dose to the patient although this decrease is somewhat less dramatic.

At the same time as kilovoltage is increased the image contrast will generally decrease, making it more difficult to visualize small changes in tissue structure. For this reason the selection of kilovoltage is always a compromise between dose reduction and loss of contrast. A good working approach is to select the highest kilovoltage that still provides acceptable diagnostic contrast. It must also be remembered that some control of contrast is also available in the choice of film and in film processing technique. Use of a lowered kilovoltage to make up for inadequate film processing contrast is

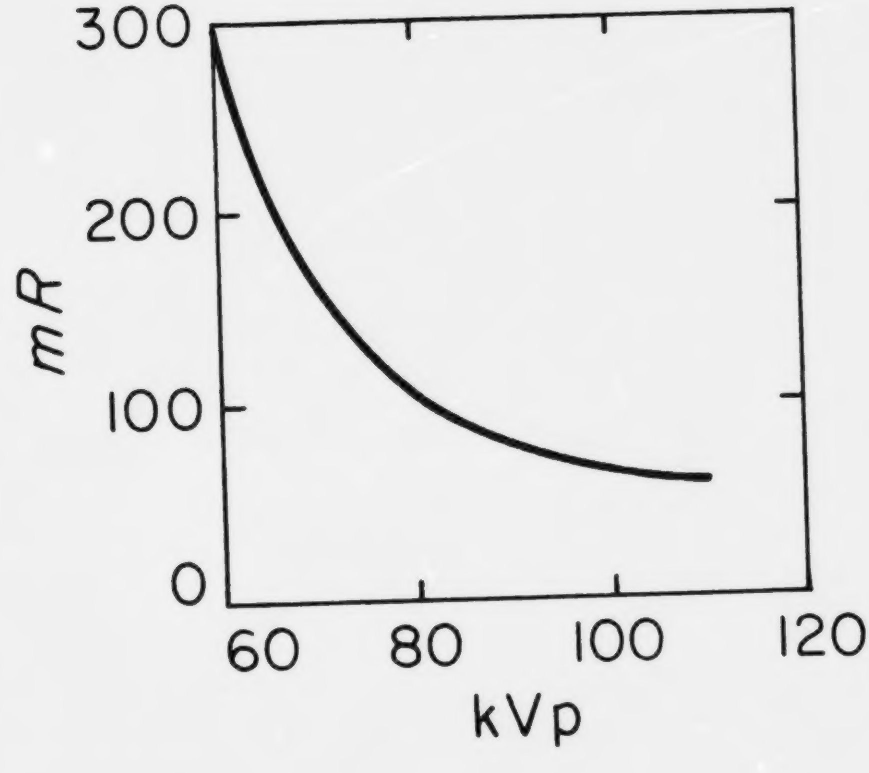

Figure 3-1 Effect Of Kilovoltage On The Entrance Exposure Required To Obtain Constant Film Density (20 cm phantom)

a common error in imaging practise which can result in unnecessarily high patient exposures.

Table 3-1 can be used as a guide to selection of kilovoltage. It may, in the case of large patients, be necessary to increase these values in order to obtain adequate penetration. On the other hand, it is justifiable in the case of special techniques to use lower kilovoltages if the diagnostic value so obtained can be identified.

Table 3-1 Recommended Minimum Kilovoltages For Standard Radiographic Views (for average size patient)

| VIEW | THICKNESS (cm) | KILOVOLTAGE |
|---|---|---|
| PA Chest | 23 | 120 |
| Lat. Skull | 15 | 75 |
| AP Cervical Spine | 13 | 70 |
| AP Thoracic Spine | 23 | 75 |
| AP Lumbar Spine | 23 | 75 |
| Lat. Lumbar Spine | 32 | 95 |
| AP Abdomen and IVP | 23 | 75 |
| Full Spine | 23 | 85 |
| AP Foot | 8 | 70 |

### 3.3.4 Filtration

The output of an unfiltered x-ray beam contains a broad spectrum of energies varying from near zero to a value dependent on the peak kilovoltage applied to the tube. The lowest energies in the x-ray beams serve virtually no useful purpose since the x rays will not get through the patient to produce an image. The primary purpose of filtration is to remove these low energy x rays which would otherwise contribute an unnecessary radiation dose to the patient.

The most common material used as a filter in radiology is aluminum. For examinations other than mammography and chest radiography it is common to add between 1 and 3 millimeters of aluminum (additional to the inherent filtration of the x-ray tube and that of collimator) to the x-ray beam in order to reduce patient dose. The amount of additional aluminum used is a compromise between reduction of dose and reduction of image contrast since as more aluminum is added there is a reduction in the amount of intermediate energy x rays in the beam which contribute toward image contrast. Generally, as kilovoltage is raised more aluminum can be placed in the x-ray beam without excessive degradation of image contrast.

The "quality" of the x-ray beam can be characterized in terms of its half-value layer (HVL). The measurement of half-value layer is discussed in Section 5.4. Minimum acceptable values of half-value layer for different kilovoltages are specified in Table 8 of the Regulations. If the half-value layers of x-ray beams used in a facility lie below the values given in Table 8 then it is likely that either the kilovoltage calibration is in error or there is insufficient filtration of the x-ray beam. As a rule of thumb, for general abdominal radiography at 80 kVp and higher an added 2 mm aluminum filter in addition to the inherent filtration of the tube and collimator is acceptable.

### 3.3.4.1 Other filters

#### Mammography

For film-screen mammography a very low energy x-ray beam is required. For this reason kilovoltages of 30 or lower are generally used. As well, a molybdenum target x-ray tube is often selected since this yields a beam in which a large component of x-ray emission is in the 20 keV energy range. Aluminum filtration is inappropriate for film screen mammography with a molybdenum tube since such a filter will remove x rays in the useful energy range and reduce image contrast. For film-screen mammography, it is recommended that a molybdenum filter of at least 0.03 mm thickness be used to obtain an acceptable compromise between patient dose and image contrast.

For xeromammography, a tungsten anode x-ray tube must be used.* Added aluminum filtration is used to reduce patient dose. A molybdenum anode tube and/or molybdenum filters are not suitable for xeromammography as their use will result in high doses to the breast and/or excessive loading of the x-ray tube.

#### Chest

For chest radiography at 120 or 140, kVp a copper filter has been found to be useful. A thickness of 0.25 to 0.35 mm is effective in reducing patient dose, maintaining contrast while not imposing an excessive increase in x-ray tube heat loading. If the filter must be removed and replaced frequently it should be protected by lamination to a thin (0.5 mm) sheet of plastic or aluminum.

#### Graded Filters

In some procedures such as full spine imaging for scoliosis the variation in patient attenuation along the length of the image is too great to allow an optimum exposure to be obtained along the entire film. To compensate for this, a technique that has been widely used is a set of screens of different sensitivities; more sensitive in regions where the body is more attenuating and less sensitive where the body is thinner. Although this approach does provide images of reasonable quality, the use of insensitive film screen systems results in unnecessary dose to the patient. A better way of resolving this problem is to use a set of filters of varying thickness to taper the x-ray beam so that it is most intense where the patient is highly attenuating and less intense in areas corresponding to the thinner parts of the patient. When a graded filter is used in this way, patient dose is reduced for a given level of image quality and only a single speed of film screen system is required.

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*See Safety Code, Ontario Regulation 511/85, Section 18.

## Iodine contrast examinations

These examinations can involve high exposures, especially in large patients if low kilovoltages (eg 65kVp) are used to provide contrast. In examinations such as the IVP where the contrast of iodine is the main feature of interest it has been found effective to use a special filter of a material called holmium. When used with a kilovoltage of approximately 80 to 85, a holmium filter results in an x-ray beam containing a high proportion of x rays in the energy range just above 34 keV; x rays at lower and higher energies are largely removed from the beam. Since iodine has a sudden increase in its x-ray absorption just above 34 keV such an x-ray beam will be heavily absorbed by any iodine present. The surrounding tissues will not display such heavy absorption and, therefore, good contrast is obtained (Villagran, 1978). Because the kilovoltage can be increased when the holmium filter is used it has been found in some departments that such contrast improvement is available together with a reduction in patient dose.

Other departments have found that use of a well-filtered x-ray beam (H.V.L. of about 4 mm Aluminum) and 75 kVp will still provide adequate contrast and avoid the cost of the holmium filter and the increase in tube loading which it necessitates. The heavy aluminum filtration allows exposures to be kept low.

Other specialized filters have been suggested for certain examinations in order to reduce dose, increase contrast or both. For further information the reader should consult the literature (e.g. Wang, 1984).

## 3.4 Collimation

As mentioned previously, the risk of radiation-induced disease is probably related to the amount of tissue irradiated. Collimation refers to the limitation of the size of the irradiation field at the patient. The following principles relating to collimation should be kept in mind:

**1. The primary x-ray beam should be defined by pre-patient collimation, such that when it enters the imaging system it does not extend beyond the active area of the image receptor.**

**2. The irradiated area should be only as large as is required to cover the tissue of diagnostic interest in the image. As well as minimizing risk, this action reduces the amount of scattered radiation produced and tends to improve image contrast.**

## 3.5 Anti-scatter Device

In most radiological examinations the main interaction between the x-ray beam and the patient is by scattering of the x rays. Much of this scattered radiation escapes in the same direction as the primary, image-forming beam and has the effect of reducing image contrast and adding quantum noise to the image. For many examinations, therefore, an effort is made to reduce the amount of scattered radiation reaching the imaging system. The two means of achieving this are the use of an "air-gap" between the patient and the image receptor and by the use of a grid.

While the air-gap technique is effective, in reducing scatter, the gap causes some image magnification which is not always acceptable. The air-gap technique is used mainly for chest radiography with a 10 foot focal spot-to-image receptor distance and for intentional magnification radiography.

Of much more common use is the grid, which consists of thin strips of lead arranged to allow most of the primary x rays to pass through the grid while some of the scattered x rays are rejected. The grid can have a significant effect in improving image contrast but always at the expense of increased patient dose. Patient dose must be increased (by a factor of about 1.5-4) when a grid is used for three reasons:

1. Some of the primary x rays will hit the strips of lead in the grid and will not pass through to reach the imaging system.

2. The grid strips must be separated by some material, usually fibre or aluminum and this "interspace" material will absorb some of the primary radiation.

3. When the grid removes some of the scattered radiation there will be less total radiation reaching the imaging system and to obtain a film of the same optical density this radiation must be replaced. This is done by increasing the exposure to the patient.

Grids are characterized by their "grid ratio" i.e. the ratio of the thickness of the grid (parallel to the direction of travel of the x rays) to the width of the channel between adjacent lead strips. The higher the grid ratio the smaller will be the acceptance angle for scattered radiation from the patient and the more efficient will be the rejection of scatter. The grid ratio may be increased by using a thicker grid in which case the inefficiency due to loss of primary radiation in the interspace material increases. Another way of increasing grid ratio is to narrow the distance between adjacent lead strips. When this is done, the thickness of the individual strips must be reduced, or else proportionally less of the grid's surface area will be open to the acceptance of primary radiation.

The number of grid lines (the strips) per centimeter is the second parameter which characterizes grids. The third important factor is the interspace material. In general, aluminum interspace grids will absorb more of the useful primary radiation than will fibre grids. On the other hand the aluminum grids tend to be more rugged and where this is an important factor may be more practical.

The fraction of the radiation leaving the patient which consists of scattered x rays does not change drastically with kilovoltages above about 40 kVp. The grid does, however, become slightly less efficient in terms of scatter rejection as the kVp is raised. For this reason if relatively low kilovoltages (90 or less) are used it has been found in many facilities that grids with ratios as low as 8:1 are acceptable. For examinations carried out at higher kilovoltages, ratios as high as 10:1 or 12:1 may be desirable.

For some examinations where image contrast is not lacking, for example when contrast agents are used, the grid might well be eliminated completely. This is especially true in some types of fluoroscopic examinations. It is useful in those cases to have equipment where the grid can easily be moved in and out of the x-ray beam with minimal time or effort. Finally, as a dose-saving measure in very small patients and especially paediatric examinations, it is often acceptable to eliminate the grid completely for both fluoroscopy and radiography.

## 3.6 Image Receptor

Probably the major factor controlling patient dose is the sensitivity or speed of the image receptor i.e. the screen-film combination for radiography and the image intensifier-camera chain for fluoroscopy and image intensified photofluorography (photospots).

### 3.6.1 Film-screen systems

For film-screen systems, the sensitivity can be described in two ways: by a speed index and in terms of the radiation exposure to the screen required (under specified processing conditions) to yield a net optical density of 1.0 on the film. The speed index system assigns a value of 100 to the so called "par speed" film-screen combination employing calcium tungstate screens which was the standard combination before the introduction of rare earth image receptors. Under this system film-screen combinations are now available encompassing the speed range of 25-1200; a factor of 48. Use of the fastest film-screen pair with all other factors unchanged would allow an exposure reduction of 12 from the "par speed" combination.

Clearly it is critical in choosing a combination that the image quality, expressed in terms of spatial resolution, contrast, and noise (see Section 2.2), be compatible with the examination for which the combination is to be used. Generally as the speed of the image receptor is increased, resolution will decrease and at the same time noise or mottle will be more apparent. The compromise between dose and image quality is ultimately dependent on the type of examination (purpose of the exam, site in the body, age and pregnancy status of the patient) and on the judgement of the professional responsible for extracting the information from the film. Some guidelines, however, can be drawn from the published literature where the results of evaluation of screen-film combinations have been presented and Table 3-2 provides recommendations for the selection of speed of film-screen combinations for commonly-performed procedures.

For film-screen mammography a single, high-resolution back screen (film emulsion between breast and screen) and a single emulsion film have been widely accepted. Specialized products for this purpose are available. Double screen systems designed specifically for mammography and employing anti-crossover double emulsion film have recently been introduced. These may be found acceptable for further reducing doses to the breast especially for grid or magnification mammography. Because mammography is carried out at a much lower kilovoltage than general radiography the speed designations in Table 3-2 are not applicable. In general, the screen should be similar to that used for detail radiography providing a high-contrast spatial resolution of at least 14 line pairs per mm.

When new higher speed imaging systems are used with older x-ray equipment, the equipment may require modification, eg. reduction of tube current, or adjustment of the automatic exposure control, in order to yield satisfactory results.

Table 3-2 Recommended Speeds Of Screen-film Combinations For Various Examinations

| | SPEED INDEX | mR (at cassette) for net OD of 1.0 |
|---|---|---|
| Gastrointestinal | 400 | 0.32 |
| Excretory Urography | 400 | 0.32 |
| Chest | 100-400 | 0.32-1.25 |
| Angiography | 800 | 0.16 |
| Pediatrics (except neonates) | 400 | 0.32 |
| Neonates | 100 | 1.25 |
| Lymphography | 800 | 0.16 |
| Pelvimetry | 400-800 | 0.16-0.32 |
| Bone | | |
| Extremities | 80-100 | 1.25-1.6 |
| Trunk | 400 | 0.32 |

### 3.6.2 Fluoroscopic image intensification systems

Image intensification systems can be characterized by the x-ray absorption efficiency and gain of the image intensifier tube. Two generic types of image intensifiers are commonly used: those with zinc cadmium sulphide input phosphors and those with caesium iodide phosphors. New equipment is furnished with the latter type, which has both higher x-ray absorption efficiency and higher gain than the former. This means that to obtain a given brightness in the image produced, less radiation is required with the caesium iodide systems; possibly a reduction in exposure rate by a factor of 3-4.

In image intensifier systems which employ television or a small format film camera, several other parameters are also important. The light from the image intensifier tube is usually coupled to the television or film camera via a lens system. Any factor, such as dust in these optics or an intentional restriction in the light path, such as an iris or attenuating filter, will reduce the light reaching the camera so that for the same amount of light to reach the camera, more radiation exposure to the patient is required. In systems using "automatic brightness control" the x-ray exposure is adjusted automatically to achieve a preset brightness level.

Apertures are commonly used in the optical path to improve the resolution and uniformity of the intensified image and to control the level of quantum noise. Most image intensifier systems allow a choice of aperture size in the optics for both the television camera and the small-format camera. Under conditions where the ultimate resolution is not critical and quantum noise is not a major concern, a marked reduction in radiation dose can be achieved easily and cheaply by choosing a large diameter aperture in the optics system. An acceptable operating point can be determined with the assistance of the equipment service engineer using patient-equivalent phantoms.

### 3.6.2.1 Variable fluoroscopy exposure rate controls

Some modern fluoroscopy equipment is equipped with a variable exposure rate control which allows, for the same brightness of fluoroscopic image, a range of x-ray exposure rates to the patient. Since the image intensifier and video system amplify the image brightness the required x-ray exposure rate depends on how much amplification is actually used. By increasing this amplification, less radiation is required to produce the fluoroscopic image.

However, when this is done, since fewer x-rays are used the quantum noise will be increased significantly. On the other hand when the amplification of the image intensification system is decreased, more radiation is required to produce the image (i.e. higher patient dose) and the quantum noise is thereby reduced.

A low-noise image is not always required during the fluoroscopic examination; for example for positioning purposes or when the image is of very high contrast a more mottled image is acceptable. Considerable dose saving to the patient can be accomplished by using such variable exposure rate controls and selecting a low exposure rate when the resultant image is acceptable and going to the high exposure rate mode only when the ultimate in image quality is required.

### 3.6.2.2 Mobile C-arm image intensification systems

These systems are quite common and if used correctly can produce high quality images at low exposure rates. These systems are generally designed to have a fixed distance between the focal spot and the image intensifier. Often this distance is less than 1 metre. This short distance and the fact that the patient can be placed very close to the x-ray source can give rise to rather high exposures to the patient. In the interest of reducing patient exposure it is important that the patient be placed as close as possible to the image intensifier. Also, it is important to ensure that systems with short x-ray source-to-image intensifier distances only be used when it is not feasible to use permanent equipment for these examinations. For additional information on protection of personnel using portable C-arm systems please see Section 3.9.2.

## 3.7 Image Processing

Image processing is the conversion of a latent image in chemical, electrostatic or electronic form into an image which can be perceived by the human observer. By far, the most common form of image processing in radiological imaging is the chemical photographic development process.

Depending upon the variables of photographic processing, i.e. type and activity of the chemicals, development time and temperature, the resultant image can vary tremendously in terms of contrast and of the amount of radiation required to produce an acceptable visible image. Improper film processing is probably the most frequent cause of excessive radiation exposure to the patient from radiography. In order to optimize film processing the type of processing chemistry should be appropriately matched to the film product and the advice of the film manufacturer as to proper processing should be sought.

Information on quality assurance procedures for image processing is given in Chapter 5, Section 5.1.

## 3.8 Viewing Conditions

Once a high quality image has been produced it is important that it be viewed under conditions that allow optimum perception of the diagnostic features of the image. Viewing conditions have a considerable effect upon the apparent contrast of the radiograph. Among the factors of importance are: ambient light conditions, the intensity and uniformity of the view box, viewing distance and observer fatigue.

(a) Ambient light. Since radiographs are viewed by transmitted light it is important that almost all of the light reaching the eye of the viewer be light that has passed through the film. If room lighting conditions are such that light is incident on the viewer side of the film then this light will reduce the apparent contrast of the image. For this reason the ambient light in the viewing area should be subdued. The restriction of light from surrounding view boxes significantly improves observer performance (Alter,1982). It is, therefore, advisable to switch off or mask adjacent view boxes whenever possible and, in some cases, even to mask the radiograph being viewed, except for the area of interest.

(b) Intensity and uniformity of illumination. It is also most important that the view box be uniform in intensity since any changes in view box intensity will give erroneous impressions of variation of film density. The eye is able to detect small degrees of contrast most effectively at a moderately high level of illumination. View boxes tend to become dimmer over time due to accumulation of dirt or dust on the viewing surface and because of gradual fading of the intensity of the illumination source. The brightness of view boxes should be monitored regularly and view boxes should be cleaned and/or re-lamped when obvious changes in brightness or uniformity have been detected.

A brightness meter used for photography is useful for monitoring view box performance. Brightness can be checked by making a measurement in the centre of each box. Boxes should be monitored for brightness changes over time and also should be intercompared within the facility.

Uniformity of illumination can be easily checked by making multiple measurements in different regions of each viewbox.

It has been shown (Kundel,1977) that the false positive rate for lesion detection increases with increasing mean film density. For lesions whose contrast is 10%, the true positive rate of detection begins to fall when the film density is greater than about 2.0. This degradation is not due to density per se but to the decrease in light intensity reaching the eye; hence the advantage of viewing high-density areas through a bright light.

(c) Viewing distance. For lesions of 1.5 cm diameter the detection accuracy was found to be independent of viewing distance within the range 45-180 cm (1.5 - 6 ft). (Kelsey,1981). However, for smaller (1.0 cm diameter) lesions the observer accuracy increased with increasing viewing distance in the range 45-90 cm (1.5 - 3 ft) and thereafter decreases.

(d) Observer fatigue. It is widely believed that observer performance decreases with fatigue and this is true for studies that measure attention and diligence, i.e. where the observer concentrates steadily on the task for 30 minutes or longer. However, where the periods of observation are short and intermittent, tests have shown that there is no significant difference between the performance of a rested observer and of the same observer fatigued at the end of a long working day (Christensen,1977).

(e) Search strategy. Several investigations have shown that an observer's performance does depend to some extent on the "strategy" he or she adopts to search for lesions in the image. This subject lies outside the scope of these Guidelines and the interested reader is advised to consult the literature. Suggested starting points are (Parker,1982, and Christensen, 1981).

## 3.9 Other Factors

### 3.9.1 Patient positioning

When the risk to the patient from a radiological procedure is being considered the critical concern is not actually the "dose to the patient" but the dose to the radiation-sensitive sites within the patient. Some tissues are quite radiation-resistant and are not a major concern whereas others such as the breast, thyroid, lung and active bone marrow, as well as the embryo and fetus in pregnancy, have demonstrated sensitivity to the effects of radiation.

In some cases, when all other technical factors of an examination have been optimized, it is possible to reduce the dose to such critical sites by choice of positioning of the patient. The principle here is simple: for the same amount of radiation reaching the image receptor, parts of the patient further from the x-ray tube receive less radiation than those parts which are closer to the tube. In cases where the patient can be examined in either orientation, positioning such that the thyroid, breast, lungs, bone marrow or the fetus are on the exit side of the radiation beam is desirable. In this way these critical sites receive less radiation because of both inverse square law attenuation and the shielding of other tissues which lie between them and the x-ray source.

### 3.9.2 Radiation protection for personnel in areas where fluoroscopy is being performed

Radiation exposure to personnel from fluoroscopy is almost entirely due to scattered radiation originating within the patient. A strategy toward radiation protection of personnel can be developed by considering that the scattered radiation is most intense on the side of the patient which is facing the x-ray tube. The side of the patient which is facing the imaging system is emitting only scattered radiation that has been heavily attenuated within the patient and it is therefore at a much lower level. The amount of scattered radiation to which personnel may be exposed, therefore, depends upon the design of the fluoroscopic system.

When the x-ray tube is beneath the patient table and the x rays are directed upward most of the scattered radiation from the lower side of the patient will be directed toward the floor and can easily be intercepted by the shielding incorporated in the table by the scatter curtain mounted on the intensifier carriage or by lead aprons which must be worn by personnel in the room. When the x-ray beam is directed laterally, as in the case of C or U-arm units an intense field of scattered radiation will exist on the side of the patient toward the x-ray tube.

When working near the patient under such circumstances such additional protective equipment as thyroid collars, attenuating eye glasses or movable floor- or ceiling-supported transparent shields should be provided. If possible, personnel should be located on the imaging system side rather than on the x-ray tube side of the patient. If, as should be the case in good practice, the primary beam is confined to the area of the image intensifier then the patient will then act as an excellent shield of the scattered radiation and the exposure to personnel will be reduced.

Similar comments apply to the situation where the x-ray source is located above the patient and the beam is directed downward as in many special-procedure rooms. Here, however, there is less flexibility as to the location of personnel and protective shielding is especially important. It is suggested that anybody who must be in the room during the exposure but who is not required directly adjacent to the examination table stand as far as practical away from the patient in the room.

## 4 INDEXED GUIDE TO THE REGULATIONS

The standards which have been set down in the Regulations have been established to guarantee minimum levels of performance for certain aspects of radiological imaging. In general the standards relate to factors controlling radiation dose to the patient or to those influencing the image quality of an examination. While some facilities may in fact operate to higher standards, those given here are considered to be a minimum for acceptable performance.

In this section, comments are related to the individual regulations under the Act and are designed to aid the facilities in complying with the Regulations. It should be noted that not every subsection of the Regulations is explicitly covered in this Chapter since certain regulations, e.g. Sections 1-5, are self-explanatory.

| SECTION IN REGULATIONS | |
|---|---|
| 1 | Definition of Terms |
| 2 | Information Required to File an Application to Install Diagnostic X-ray Equipment |
| 3 | Protective Barriers and General Regulations to Protect Personnel, the General Public, and Radiation-sensitive Materials |
| 4 | Operator Qualifications - Dental , Medical<br>Training Course Requirements for Operators of X-ray Equipment |
| 5-(1) | Operation of X-ray Equipment by Trainees |
| 5-(2) | Radiation Protection Officer - Exemption to Allow Radiological Technician to Act as R.P.O. where a Radiologist is not on Staff |

# 6 CLASSES OF RADIATION PROTECTION OFFICER

## Formal Qualifications

Subsection 9.-(1) of the Healing Arts Radiation Protection (HARP) Act requires the owner of an x-ray machine used for irradiating human beings to designate a suitable person as the Radiation Protection Officer (RPO) for the facility concerned. The basic qualification of the RPO, as set out in the Act, is legal membership of the relevant profession, i.e. medical, dental, podiatric or chiropractic*. Also, Section 5-(2)of the Regulations provides an exemption from subsection 9.(1) of the Act, where there is no suitable person with a relevant qualification: in such cases a radiological technician registered under the Radiological Technicians Act and who, in the opinion of the Director of x-ray safety is competent to act as RPO, may be designated as the RPO.

## Additional Qualifications

While neither the Act nor the Regulations specifies any formal qualification additional to that stated above, the duties of the RPO are such that some special training is highly desirable. The extent of this training will depend on the type and size of the facility, the nature of the equipment and whether quality assurance tests are carried out by the RPO himself or delegated to another person. It is strongly recommended that, as a minimum, the RPO satisfy himself that his understanding of the topics listed under "Training of the R.P.O." (below) is such that he is familiar with both the technical and clinical aspects of the various tests carried out in the facility and able to formulate policies and recommendations on the basis of these tests.

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*In addition, a proposed amendment to the Act may permit a qualified Medical or Health Physicist to act as RPO.

## 7 DUTIES OF THE RPO

The responsibilities of the RPO are set out in subsection 9-(4) of the Act and in Sections 7-(1) to 7-(14) of the Regulations. These duties may be summarized as follows.

### 7-(1)

It is the responsibility of the RPO to ensure that x-ray equipment is operated only by those people who are considered qualified under the Act and its Regulations;

### 7-(2)

It is the responsibility of the RPO to establish and maintain procedures and tests for the x-ray machines and equipment to ensure compliance with the Regulations.

### 7-(3) Protective Accessories

It is the responsibility of the RPO to ensure that appropriate accessories are available to shield those who are likely to be exposed to greater than normal environmental levels of radiation and because of the nature of their task cannot be protected by the permanent shielding fixtures of the facility.

In situations where staff may have to be in the x-ray room and cannot be protected by fixed radiation barriers such as shielded walls, the facility must provide lead aprons, gloves and/or attached lead drapes. Protective accessories must be equivalent in x-ray absorption to at least 0.5 mm lead at 150 kVp. Table 4-1 indicates the x-ray transmission of such accessories for beams of different kilovoltage.

In addition, patients should be provided with protective devices e.g. breast shields, eye protection where a significant exposure to these sites would otherwise result and where such shielding does not interfere with the radiological procedure.

**Table 4-1 Transmission Of X-rays Through Material of 0.5 mm Lead Equivalent At 150 kVp**

| kVp | Transmission factor |
|---|---|
| 150 | 0.06 |
| 100 | 0.012 |
| 70 | 0.0009 |
| 50 | 0.00001 |

Values given in Table 4-1 are adapted from NCRP Report #49 (NCRP, 1976) which are based on attenuation of the primary radiation beam which has passed through only the normal filtration of the x-ray tube. Measurements suggest that these values may also be used for assessing the transmission of devices which protect against scattered radiation emitted by the patient. They should not be used in room shielding applications.

## 7-(4) Acceptance Testing (New Equipment)

It is the responsibility of the RPO to ensure that appropriate acceptance tests are carried out on new equipment, to verify compliance with the Federal Radiation Emitting Devices Act and its Regulations. Written test results are to be forwarded to the Director of X-Ray Safety within 60 days of installation of the equipment. A sample checklist for acceptance testing under the RED Regulations is included in Chapter 6.

## 7-(5) Acceptance Testing (Used Equipment)

The RPO must ensure that appropriate acceptance tests are carried out on newly-installed used equipment to verify compliance with the HARP Act and its Regulations. Written test results are to be forwarded to the Director of X-Ray Safety within 60 days of installation of the equipment. A sample checklist for acceptance testing of used equipment is provided in Chapter 6;

## 7-(6), 7-(7) Records

It is the responsibility of the RPO to ensure that appropriate records of all tests and measurements relating to quality assurance and acceptance are maintained for a period of at least six years and are made available on request to authorized persons, including the owner of the facility, the staff and the Director of X-ray Safety;

## 7-(8), 7-(9), 7-(10) Quality Assurance Programme

It is the responsibility of the RPO to establish an appropriate quality assurance programme which includes testing of at least those parameters listed in Tables 3, 4, or 5 of the Regulations and to ensure that the programme is carried out at intervals prescribed in whichever of these tables is applicable to the facility.

The radiological imaging process is a complex system involving many variables which include: a) the performance of the x-ray machine in emitting a certain quantity and quality of radiation, b) sensitivity, resolution, noise and uniformity of the image receptor in detecting the information carried by the x rays transmitted through the patient and c) similar variables in the image processing step where the information is converted to a visible image. Each of the many components must be optimized in order to produce a high quality diagnostic image with the lowest reasonably-achievable radiation dose to the patient.

Once optimized, various factors in each component are susceptible to drifting which may cause image quality and radiation dose to vary over a period of time. For this reason the various aspects of imaging performance must be monitored routinely so that the appropriate action can be taken quickly. This monitoring process is known as quality assurance (QA). It is important that a facility not rely completely on outside agencies for all aspects of quality assurance monitoring. It is simply impractical for such agencies to perform monitoring at sufficiently short intervals. While small facilities may decide that certain aspects of the quality assurance programme might be performed more successfully by trained specialists in this field it is important that certain tests, especially those of film processing be carried out in-house so that appropriate action can be taken quickly if necessary.

Recommended procedures for technical quality assurance testing are given in Chapter 5 of the Guidelines and in Gray, 1982.

## 7-(11), 7-(12) Limitation of Radiation Exposures

It is the responsibility of the RPO to ensure that radiation exposures under test conditions corresponding to specific radiological projections (views) do not exceed limits specified in Table 6 or Table 7 of the Regulations, whichever is applicable.

While not expressed explicitly in the Regulations, the spirit of the HARP programme is such that the Radiation Protection Officer would be expected to ensure that radiation exposures to patients undergoing x-ray procedures, to x-ray machine operators and other staff, and to members of the public, are As Low As Reasonably Achievable; while at the same time images are of acceptable diagnostic quality. In order to achieve this goal the RPO must advise the owner of the x-ray facility or the director of clinical services as to:

(i) measures which need to be taken to remedy any deficiencies in compliance with the Regulations;

(ii) measures which can be taken to improve the performance of the facility even when this is within the norms established by the Regulations;

iii) measures which can be taken to improve the training of staff and their participation in the QA program;

## 7-(13), 7-(14)

It is the responsibility of the RPO to advise the Director of X-Ray Safety of the occurrence of an accident involving an x-ray machine, or a radiation overexposure to a patient.

An "accident" involving an x-ray machine means a mechanical or electrical accident which results in, or potentially could result in, injury to a patient. A "radiation overexposure" means an accidental or inadvertent exposure which results in a significant additional dose to a patient.

In order to achieve clear lines of communication the RPO should maintain a liaison with the X-Ray Inspection Service of the Ontario Ministry of Health both during and between visits of Inspectors.

The duties listed above are explicit in terms of equipment performance, quality assurance and radiation exposure. Of great importance is the implied condition that these factors must be considered at all times in relation to the diagnostic quality of the images produced. The RPO must bear in mind that the sole purpose of a radiological investigation is to obtain information which is useful to the diagnosis and/or treatment of the patient's condition. A radiograph which fails to provide this information because of a deficiency in the imaging technique is an exposure wasted, even if the patient exposure is below the maximum specified in the Regulation. In implementing the ALARA principle and in advising on remedial or other measures, the RPO has to consider the likely effect of these measures on image quality as well as patient exposure.

## Training of the RPO

In order to carry out the responsibilities of RPO effectively the individual selected should have the following minimum training:

a) basic knowledge of:

(i) the physics of x rays and their interaction with matter

(i) the principles of radiological equipment (x-ray generators and image receptors)

(iii) the principles of image formation and recording

(iv) biological effects of radiation

(v) hazards associated with diagnostic radiology

(vi) protection of both patients and staff

These subjects are set out in subsection 4-(1) of the Regulations, in relation to Operator Qualifications, and are common to RPO's in any type of diagnostic x-ray facility.

b) additional specialized knowledge of the relationship between technique factors, image quality and patient dosage in the specialty in which the RPO has to operate, i.e. medical x-ray diagnosis, dental x-ray diagnosis, podiatric x-ray diagnosis or chiropractic x-ray diagnosis;

c) additional specialized knowledge of acceptance testing and quality assurance procedures in the specialty in which the RPO has to operate. The extent of the knowledge and practical training required in this section depends on whether the RPO carries out these procedures himself or delegates the task. In the latter case, the RPO should be familiar with the principles involved but not necessarily with the practical details.

d) thorough knowledge of the Healing Arts Radiation Protection Act and Regulations thereunder and the sections of the Radiation Emitting Devices Act and Regulations pertaining to x-ray equipment for medical diagnosis.

Who should be the RPO?

Preferably, the RPO of an x-ray facility should be:

(a) occupied full time in the facility

(b) in a position of authority

The RPO should be fully aware of the nature and extent of the duties involved. Even if he delegates the performance of the QA and other tests to someone else, the RPO still carries the legal responsibility for these tests and must, therefore, understand the principles involved. He should realize that, at the present time, the training which leads to a formal qualification for an RPO as required in the Act does not necessarily include the specialized knowledge required by an RPO. Nevertheless, the person appointed should either possess, or be prepared to acquire such additional expertise as may be relevant to the post.

## Administrative Aspects of The RPO's Duties

Unless the owner of the facility is also the head of the clinical service and acts as his own RPO (as in many small private offices), some conflict of outlook and/or interest may arise, especially if the RPO makes recommendations which have significant financial implications.

In order to minimize such conflicts, it is recommended that:

a) Possible areas of conflict be anticipated.

b) The RPO (if other than the Head of the Clinical Service) be a senior person having the full confidence of the owner of the facility.

c) The person undertaking the tests, if other than the RPO, be encouraged to explain the results of the tests and their significance, in as simple terms as possible.

d) The RPO be encouraged to undergo the additional training set out above, even if he himself does not carry out the Quality Assurance tests.

e) Regular meetings of all staff be called to explain the significance of QA and other tests carried out on the equipment.

## STANDARDS OF EQUIPMENT DESIGN AND FUNCTION

### 8-(3)-(a) Control of Exposure

The Regulations require that the operator have control over the initiation and termination of the exposure by means of an exposure switch and a timer or automatic exposure control device.

### 8-(3)-(b) Filtration.

An unfiltered x-ray beam can contain very low energy x rays most of which will be absorbed in the patient, contributing only to dose and not to the image. Standards for beam quality are given in Table 8 of the Regulations to ensure that these low energy x rays are removed by filtration. Note that the actual filter (type or amount) to be used is not specified but rather the minimum acceptable beam quality in terms of HVL for each range of kVp. If acceptable image quality can be obtained with beams of greater HVL than in Table 8 of the Regulations then this will allow reduction of patient exposure and is to be encouraged.

## 9 OPERATION OF EXPOSURE SWITCH

The regulations regarding the exposure switch are designed to minimize the chances of inadvertent x-ray exposure to the patient and also as much as possible to protect the operator from excess x-ray exposure. It is recognized that these regulations are not "fool-proof" because to be so would unduly limit the flexibility of operation of the x-ray equipment and might in fact make certain procedures impossible. The standards do, however, provide for equipment which, in combination with the good judgement of the operator, facilitates safe examinations.

### 9-(1)-(a) Location of Exposure Switch

The exposure switch must be located such that the operator is protected by appropriate radiation shielding when he/she activates the equipment to produce x rays. This Regulation does not apply to equipment used for procedures in which the operator must be in the x-ray area during exposure such as some fluoroscopy and special procedures (see 9-2 in Regs.). It is essential that when the operator is in the x-ray area during exposure he/she is protected by appropriate means i.e. lead apron or lead barrier and possibly thyroid collar, lead glasses or lead gloves where indicated.

### 9-(1)-(b) Length of Cables for Exposure Switch

Some x-ray equipment must be operated in the absence of fixed x-ray shielding barriers. When, as should be the case, the primary radiation beam is completely absorbed by the image receptor support, the main source of radiation exposure to operators and other personnel will be scattered x rays originating in the patient. In order to minimize dose to personnel from this radiation, the design of the equipment must allow the operator to stand a reasonable distance from the patient. The Regulations, therefore, require that if the exposure switch is on a cable, that cable must be at least 3 metres in length.

## 9-(4) Serial Changers

On serial changer operation the exposure switch must allow interruption of the exposure by the operator at any time.

## 9-(3), 9-(5) Deadman Action of Exposure Switch

As additional safety features the equipment must be designed such that the exposure switch requires continuous pressure to continue an exposure or sequence of exposures. Similarly a foot switch must require sufficient pressure that it will not allow an unintended x-ray exposure if the switch is overturned on the floor.

### "Normal Range Of Use"

Most x ray equipment is designed such that it will operate over a very large range of kilovoltage, tube current and exposure time. In certain applications equipment is restricted in its mode of operation to a limited range of these settings. Under such conditions the HARP regulations specify that the equipment need only meet standards over its "normal range of use". This allows the effort of calibration to be directed toward the areas which will have the greatest effect on patient dose and image quality can considerably reduce the cost of calibrating equipment. At the same time equipment which is only calibrated over part of its possible range of control settings must be clearly marked to that effect and no attempt should be made to use it under conditions in which its performance is not predictable.

## 10 EXPOSURE TIMING

### 10-(1), 10-(2) Timer

All radiographic equipment must have an exposure termination device which causes the exposure to terminate after either 1) a fixed pre-set time, 2) a pre-set value of mAs, 3) a pre-set number of pulses from the power supply or 4) when an automatic exposure control device has detected a pre-determined quantity of radiation.

### 10-(3) Timer with "ZERO" or "OFF" Positions

These standards are intended to apply specifically to radiographic equipment.

### STANDARDS OF FUNCTIONING

In order to perform high quality radiological imaging at the minimum dose to the patient it is important, among other things that the equipment perform in a reliable and predictable manner. Many of the regulations in subsequent sections are designed to address this point. These regulations set standards for the reproducibility, accuracy and predictability of the output of x-ray machines. Methods for testing equipment are outlined in Chapter 5.

## 12-(2)-(a) Reproducibility of Radiation Exposure Output

The standards for reproducibility of diagnostic radiographic x-ray machines (except for dental, chiropodic or mammographic) are that for technique factors in the normal range of use of the equipment (see Guidelines 7.3.1) for a test of 10 consecutive exposures measured within an hour the coefficient of variation is no greater than 0.08 and that no individual x-ray exposure may differ from the mean value of 10 measurements by more than 20% of the mean value. (see general discussion on reproducibility in Chapter 5).

## 12-(2)-(b) kV Accuracy

With all diagnostic x-ray machines (except dental, chiropodic or mammographic) the average over an x-ray exposure of the peak kilovoltage supplied to the x-ray tube must correspond to the selected value of peak kilovoltage to within +/- 8%. This means that individual peaks in the waveform may vary from the selected value by more than 8% but the average over the exposure time must be within this tolerance. While kilovoltage is not explicitly included in the mandatory quality assurance programme, its accuracy should be checked regularly and especially after any servicing which could alter the kilovoltage calibration. When half-value layer measurements are made very carefully as part of the quality assurance programme they will reveal any significant change in kilovoltage.

## 12-(2)-(c) Minimum Exposure Time

The exposure timer must be designed so that it can be set to provide exposures as short as 1/30th of a second or 5 mAs whichever is greater.

### 12-(2)-(d) Timer Accuracy

The Regulations currently specify an accuracy of exposure time of ± 10% except for dental, chiropodic or mammographic units. For timer settings at or below 1/30 s (2 pulses or 33 ms), the accurate measurement of exposure time is difficult and greater emphasis should be placed on output consistency than on absolute timer accuracy. For methods of testing timer accuracy see Section 5.8.3.

### 12-(2)-(e) Timer Reproducibility

The timer must comply with the same reproducibility standards as given in Section 12-(2)-(a) of the Regulations. Timer reproducibility can be measured using the same equipment used to determine timer accuracy. It is usually unnecessary to make 10 measurements in order to determine whether equipment is performing in a reproducible manner (see Guidelines 5, Section 5.5.1). Only when it is necessary to document failure of compliance of equipment with the Regulations or with specifications is such a complete test required.

### 12-(4) mA Linearity

When radiographic equipment is used in the manual exposure mode (i.e. without automatic exposure termination) it is important that adjustment of time or milliampere technique factors results in predictable variation of output of the x-ray equipment. For manual exposure technique, output is required to vary linearity with both tube current and exposure time. If this is the case then at a fixed kilovoltage the x-ray exposure measured at a particular position divided by the number of milliampere seconds selected will yield a constant value independent of the particular setting of the timer or the tube current selector. The standard expressed in the Regulations is that when exposures are made at fixed kilovoltage and at "adjacent" tube current settings , the output in mR per mAs determined at these two settings does not differ by more than 1/10th of the sum of the mR per mAs values at the two settings.

In practice this standard provides for a tolerable non-linearity of about 20%.

Since mA linearity is particularly important between mA stations which might be selected in choosing the technique for a particular radiographic procedure, it is suggested that linearity might be tested for all the mA stations within such a group.

### 12-(5) mAs Linearity

Where equipment is designed so that only the mAs can be selected or where there is a continuous rather than stepped range of mA settings then the same standard as expressed in Section 12-(4) applies except that tests are to be performed at mAs settings differing by at least a factor of 2.

## 13 TUBE LEAKAGE

These requirements set a limit on the x-ray leakage from the tubehead. Although this leakage should be measured and recorded at installation, all modern tubeheads easily meet this requirement. If, however, there is evidence of alterations to the tubehead (eg. holes drilled etc), a new survey should be made. Since highly specialized test equipment is required to perform this test accurately, this work should be done by an expert in radiation monitoring such as a medical physicist. A quick test, however, can be done by blocking the x-ray output of the useful beam by closing the collimators and adding additional lead (1/4") in front of the collimator if necessary and monitoring the area about the x-ray tube with a survey meter.

## 14-15 COLLIMATION

Standards and tests for collimation are discussed in Chapter 5.

# 16 FLUOROSCOPIC X-RAY MACHINES

## 16-(1)-(a)-(i) Image Intensification

The Regulations require that all fluoroscopic x-ray machines incorporate image intensification. As well the equipment must be designed such that when it is in operation the entire primary beam of x rays is intercepted by a radiation shield.

## 16-(1)-(a)-(ii), 16-(1)-(b), and 16-(2) Interlocks

Stationary and mobile fluoroscopy equipment must be designed such that x-rays cannot be produced unless the image receptor is in place. Subsection 16-(1)-(b) is waived only in special purpose applications where this is not feasible (see 16-(2)).

## 16-(1)-(c) Fluoroscopy timer

An important factor contributing to patient dose is the amount of time used for fluoroscopic imaging. The required time depends upon the type of procedure and the many particulars relating to an individual patient. It is, therefore, not appropriate to regulate exposure time. It is, however, important to maintain some measurement of exposure time because often the radiologist would otherwise be unaware of the amount of radiation used for the procedure. The Regulations, therefore, require fluoroscopy equipment to be provided with either (1) an audible signal to indicate completion of a pre-set time not to exceed 5 minutes of fluoroscopy; the signal to continue whenever x rays are produced after the time has expired until the timer is reset or (2) a circuit which will cause the x-ray exposure to terminate after this pre-set time and not allow additional exposure until the timer has been reset.

Of these two alternatives the first is much more suitable since it is undesirable to interrupt an x-ray exposure during an important diagnostic procedure. The second provision has been allowed only to avoid making non-compliant a large number of pieces of equipment now in use.

## 16-(1)-(d) Tube current indication during fluoroscopy

Since much of fluoroscopy is performed under automatic control there is little indication regarding the actual amount of radiation being used during the procedure. It is therefore important to have some monitor of machine output. The Regulations require an indication of fluoroscopic tube current to act as a monitor of tube output. If the tube current is excessively high this is an indication that the imaging system may not be functioning correctly or that the kilovoltage is too low. In either case this is an indication of the need for further quality control tests.

## 16-(1)-(e) Minimum target-skin distances for fluoroscopy

For a given kilovoltage, filtration and tube current the exposure rate to the patient depends critically upon the distance of the patient from the x-ray source. The effect on exposure rate is predicted by the inverse square law which predicts that cutting the distance from the x-ray source to the patient in half causes a four-fold increase in exposure rate. For a fixed focal spot to image receptor distance it is always desirable in the interest of minimizing dose to place the critical parts of the patient as far as possible from the x-ray focal spot. This regulation sets standards for the minimum target to skin distance which can be used for fluoroscopic equipment. These are: 38 cm for a stationary fluoroscopic machine, 25 cm for a mobile machine and 20 cm for equipment used for special procedures which would not be possible under the previous limits. In any case it should always be attempted to maintain the greatest practical target to skin distance in the interest of minimizing patient doses.

## 16-(1)-(f) Beam restriction

The purpose of this Regulation is to ensure that:

1. The field is kept as small as possible, limiting patient dose.
2. All the useful radiation is used to produce an image.

To test compliance the centre of the intensifier should be identified with a lead marker taped to the input surface. A radiographic cassette should be placed over the intensifier and a second lead marker placed so that the two markers are superimposed. The beam-limiting device is then opened fully and a radiograph is produced. When the processed film is again placed over the intensifier and properly centred the blackened area should fall completely within the boundaries of the intensifier input surface.

Many fluoroscopic systems use collimators that produce a rectangular field. It has, therefore, been proposed that Regulation 16-(1)-(f)-(ii) be amended to allow collimators which when fully opened would produce a square radiation field of dimension equal to that of the diameter of the image receptor.

## 16-(1)-(g), 16-(3) Personnel Protective Shielding

The main source of radiation dose to those working around fluoroscopic equipment is from scattered radiation originating in the patient. To minimize such doses this Regulation provides for minimum shielding requirements between a patient undergoing fluoroscopy and a person working near that patient. On stationary equipment this must be of 0.25 mm lead equivalent at 100 kVp. Since it is not practical to incorporate such shielding on mobile fluoroscopic equipment this Regulation does not apply. It is strongly recommended, however, that wherever possible appropriate shielding should be used to reduce dose to personnel or others in the facility.

## 16-(4), 16-(5) Fluoroscopy Exposure Rates

The exposure rate required by the image intensifier for fluoroscopy depends upon the sensitivity of the image intensifier and the area on its entrance surface which is irradiated. There are two general technologies used for image intensifiers: the older zinc cadmium sulphide type and the newer, more sensitive caesium iodide type.

Many fluoroscopy systems operate on the automatic exposure rate control principle. In these systems, some signal, representative either of the amount of light produced at the output of the image intensifier or the level of the video signal is fed back to the x-ray generator to control the exposure rate to the patient. When a patient is being examined under fluoroscopy, the exposure rate will be adjusted until the image brightness reaches some predefined level. If the patient is very highly attenuating, the rate will continue to increase until it reaches the maximum setting on the x-ray generator.

For this reason the regulations set standards for two different types of exposure rates to the patient: the maximum rate which is attainable from the machine and the exposure rate to the "average patient" represented by 20 cm of water.

The amplification factor of the image intensifier is related in part to the ratio of the irradiated input surface to that of the size of the small output image of the intensifier i.e. on the "magnification" of the intensifier. The Regulations set standards for the permissible entrance exposure rates to the average patient and the maximum rate attainable for both zinc cadmium sulfide (Reg. 16-(4)) and caesium iodide (Reg. 16-(5)) intensifiers. These rates were determined under the assumption that the x-ray beam is just allowed to fill the area of the image intensifier. If the collimators are rectangular, then this condition would be represented by the smallest square field which completely fills the input circle of the intensifier with radiation. Operationally this is obtained by adjusting the collimator plates until they are just seen at the edges of the imaging field. The values for the maximum exposure rates are to be measured at the highest kilovoltage which is normally used on the fluoroscopic system. The entrance exposure rates for the average patient are to be measured under the typical operating conditions of kilovoltage for the unit.

The exposure rates discussed in this Section are based on the 9-inch mode of intensifier operation. The amount of radiation required by an intensifier to provide an acceptably bright image varies inversely as the area irradiated. A smaller intensifier will, therefore, require a higher exposure rate to produce a given image brightness. Conversely, when larger field sizes are used, lower exposure rates are appropriate.

## 16-(6) High Level Mode

The maximum rates set in 16-(4)-(a) and 16-(5)-(a) do not apply if a "high level" fluoroscopy mode is selected.

## 16-(7) High Level Fluoroscopy Controls

For various reasons it may be necessary for equipment to exceed the output exposure rate restrictions given in Sections 16-(4) and (16-(5) of the Regulations. In the case of the maximum exposure rate restrictions this may be due to excessively large patients or to the presence of highly attenuating foreign objects in the x-ray beam. With respect to the Regulations on exposure rate for a 20 cm water phantom this may be due to requirements of reduced quantum noise in order to see extremely subtle lesions. In both cases modern equipment may be provided with "high-level" controls which allow higher exposure rates to be produced.

Two designs may exist. The first is simply an overide which allows the 12.5 R/min (Regulation Section 16-(4)-(a)) or the 10 R/min (Section 16-(5)-(a)) limits to be exceeded. Such controls would not affect the exposure rate that would be emitted under automatic control on a 20 cm patient.

The second type of high level control allows the amplification factor of the imaging system to be varied so that different amounts of radiation are required to get the same image brightness. For requirements which are not critical such as localization the imaging system can be operated at a very low exposure rate producing images with rather high quantum mottle. The control may also provide for an average exposure rate level for normal fluoroscopic applications and, applicable to this Regulation, a high level control which produces very low mottle for the most demanding fluoroscopic requirements.

The Regulation requires that either type of high level control require deliberate activation and when these controls are in use that a continuous audible or visual signal to the operator of the equipment be produced to indicate that elevated x-ray exposure rates are being used.

## 17,18 Mammographic X-ray Regulations

X-ray mammography has been proven to be the most sensitive non-invasive method for the diagnosis of early breast cancer. Unfortunately not all mammography is performed with equipment capable of reliably demonstrating small lesions.

Major innovations have been introduced in the past few years to improve mammographic imaging considerably and it is essential for high quality mammography to ensure that these improvements in both equipment and technique are implemented. X-ray machines specialized for mammography have been developed to allow the optimum technique to be carried out. Some of the features of dedicated machines are: specially designed x-ray tubes, mechanical devices for achieving firm compression of the breast during the examination and automatic exposure controls to allow the correct amount of radiation to be used. In addition, film imaging systems designed especially for the requirements of mammography have been developed and should be employed. These allow the production of high quality images at the lowest radiation doses compatible with this quality; doses of a factor of two to ten times lower than those achievable a few years ago.

### 17-(1)-(a) Beam Restriction

In mammography, this requirement is to ensure that no more of the patient is irradiated than is necessary to produce a useable image. The primary radiation must be limited to the image receptor except at the chest wall where it may extend past the image receptor by up to 2% of the focal-receptor distance.

### 17-(1)-(b) Radiation Backstop

The cassette support must attenuate the beam that has passed through the breast to reduce the exposure to the patient beyond it. This is especially important in mammography which is often performed with the patient in the sitting position causing the reproductive organs to be situated directly beneath the x-ray source.

The Regulation requires that at maximum mammographic kVp and mAs settings and minimum FFD, the exposure per activation of the x-ray tube behind the receptors supporting device is less than 0.1 mR.

Accurate measurement of such low radiation exposures must be performed with highly specialized equipment.

## 17-(1)-(c) Compression of the Breast

The Regulations require that all x-ray equipment used to perform mammography be equipped with a suitable device for compressing the breast during the examination.

The application of uniform, firm compression to the breast is especially important in providing high quality images at the lowest dose to the breast. An examination performed without compression is severely compromised and in many cases is useless. Although patients may complain about the discomfort associated with compression it is absolutely essential to a high quality mammogram. By reducing the thickness of the breast the absorbed radiation dose is decreased markedly. Compression minimizes x-ray scattering which is responsible for degradation of image quality, the image is sharper, tissues are spread apart to facilitate diagnosis of suspicious lesions, anatomic motion is suspended and the image is more uniform allowing all regions of the breast to be displayed at high contrast. In order to obtain adequate compression a high degree of patient cooperation is required. This can be best achieved if the technologist carefully explains to the patient the benefits in terms of diagnostic usefulness of the image.

## 17-(3) Kilovoltage Accuracy

The accuracy of the kilovoltage must be within +/- 1 kV for selected kilovoltages of 35 or lower and +/- 4% for kilovoltages above 35. This is a considerably tighter specification than for general radiography and reflects the critical dependence of both radiation dose and image contrast on kilovoltage in the low energy range used for mammography where a 1 kVp change can have a significant effect.

Although there are a variety of methods for measuring kVp at the higher energies, the only sufficiently accurate methods available at this time involve an "invasive" measurement, ie. the measuring equipment must be connected directly to the primary or secondary of the x-ray generator circuits. Generally the equipment supplier has the test devices available for the accurate calibration of mammographic kVp. Good practice suggests that this test be done twice yearly by qualified personnel with test records kept by the RPO.

> Measurement of mammographic kilovoltage by the direct method requires connection and disconnection of cables which may at times be charged to over 50,000 volts. Unless proper precautions are taken voltages can remain on these cables even when power to the equipment has been shut off. Direct measurement of kilovoltage should only be done by personnel who are properly trained in measurement techniques and in safety procedures for working with high voltage equipment.

## 17-(4) Timer Accuracy and Output Reproducibility

Regulations for reproducibility of exposure output and timer accuracy for mammographic equipment are similar to but slightly relaxed from those for general purpose diagnostic equipment. This is to reflect the fact that many of the older mammographic units have relatively simple timers and exposures tend to be for longer times. Tests of reproducibility and timer accuracy are carried out in the same manner as for general purpose diagnostic equipment as discussed in Chapter 5, Sections 5.5, 5.7 and 5.8.

## 19-22 Regulations Specific to Dental and Chiropody (Podiatric) Equipment

For definitions of accuracy and reproducibility please see Section 5.5. For measurement of x-ray output reducibility see discussion on Regulation 12-(2)-(a). For measurement of accuracy of kVp see discussion on Regulation 12-(2)-(b). For measurement of timer accuracy see discussion on Regulation 12-2-(d). Regulations for x-ray output reproducibility and timer accuracy are similar to but slightly relaxed from those for general purpose diagnostic x-ray equipment to reflect the greater simplicity of dental and chiropodic equipment. Kilovoltage accuracy requirements of ± 8% are identical to those for general purpose equipment. Chapter 5 describes methods for monitoring dental and chiropodic equipment.

## 5 QUALITY ASSURANCE PROGRAMME

A quality assurance programme is a set of activities designed to assure that diagnostic imaging is carried out with the maximum benefit to the patient at the minimum risk. Technical quality assurance deals with those aspects involving the proper performance of equipment associated with the imaging process.

A critical aspect of technical quality assurance is the proper selection of equipment and materials for imaging since this determines the ultimate imaging performance which can be expected. Such decisions are generally made infrequently but their consequences must be accepted for many years. It is, therefore, worth expending considerable effort in this task. Some guidance in this area is provided in Section 3.1 and in Chapters 8-11. It is also essential that the specifications claimed by the manufacturers of equipment are met and,therefore, Acceptance Testing is the subject of Chapter 6.

Regulations under the HARP Act specify standards for operation of imaging systems including the x-ray generator, tube housing, collimation and some aspects of the image receptor. Some of these standards relate to the design and construction of x-ray equipment and if they are met at the time of acquisition of the equipment (see Chapter 6) will not generally require further attention. Others relate to properties of equipment operation which can drift in time and require periodic checking. This is to be done as part of the routine quality assurance programme.

The Regulations make mandatory a minimum technical quality assurance (QA) programme. The programme must include certain tests which are to be carried out at specified routine intervals with records of test results to be kept by the Radiation Protection Officer. These tests are considered to be the minimum required to monitor equipment performance. They are specified in Sections 7-(8), 7-(9) and 7-(10) and Tables 3,4 and 5 of the Regulations and include:

- tests of film processing
- measurements of entrance exposure to phantoms for various procedures performed in the x-ray facility
- tests of collimation (radiography and fluoroscopy)
- measurement of half value layer (radiography and fluoroscopy)
- tests of the photo-timing system and back up timer
- fluoroscopic exposure rates (maximum and for standard phantom)
- fluoroscopic automatic brightness control
- resolution of the fluoroscopic imaging system
- tomographic tests

If these measurements are made routinely, most problems associated with the x-ray imaging system should be revealed. Suggestions for methods of performing these tests are given in this chapter.

If the above mentioned tests show variations from one test period to the next, it is an indication that further action should be taken.

In some cases, this may require additional tests to define the exact nature of the problem. Some of these tests involve the measurement of x-ray generator parameters such as kilovoltage accuracy, timer accuracy, milliamperage linearity and detailed tests of the automatic exposure control system. Some guidelines on the performance of these tests are provided here and references are also given to publications which provide more detailed information.

IMPORTANT: The mandatory quality assurance programme specifies only a few selected tests and their required frequency. It is still the responsibility of the RPO to ensure that all of the standards in the Regulations are met even where a test is not listed in Table 3, 4, or 5 of the Regulations.

## Cost Effectiveness Of Quality Assurance Programmes

Large facilities such as hospital radiology facilities have found that the cost of personnel and equipment required to carry out a quality assurance programme is largely offset by increased life of equipment, fewer retakes and decreased "down time" and maintenance costs. The major benefit of QA of course is not easily evaluated financially but is the improvement in the quality and consistency of the diagnostic images produced. In **small facilities,** e.g. those with from one to three x-ray units and a single processor, the cost of the equipment required for quality assurance can be a more significant portion of the total budget and the provision of QA for small facilities has often been considered a problem. This need not be the case. Clearly it is not usually feasible for a small facility to purchase all QA equipment that would be used in a large radiology department, however, there are alternatives.

## Dosimeters

Dosimetry is required in all facilities both for measurement of radiation exposure or exposure rate and to determine half-value layer. Where the purchase of a general purpose dosimeter is not practical such a device could be shared among several facilities. Alternatively, small direct-reading "personal dosimeters" are relatively inexpensive and if calibrated against a more sophisticated dosimeter will normally be adequate for exposure and half-value layer measurements. Such dosimeters are simple to use. Exposure rate in fluoroscopy can be measured by measuring the exposure obtained for a fixed time, say 10 seconds, of fluoroscopy and multiplying by 6 to get the exposure per minute. Dosimetry services can also be obtained from commercial organizations who will supply film or thermoluminescent dosimeters which are returned to the company after exposure for measurement.

## Half-Value Layer

The addition of a set of inexpensive aluminum filters will allow HVL to be determined with any of the dosimetry systems discussed above using the method described in Section 5.4.1.

## Collimation

The materials required to test the x-ray beam collimation cost less than 25 cents. An easy-to-use test device and measurement method are discussed in Section 5.3.

## Photographic Quality Assurance

Because this must be done on every operational day for the processor such testing is not amenable to being performed by outside organizations. It is desirable that processing problems be quickly identified and resolved and this requires in-house monitoring. For facilities that cannot obtain the preferred sensitometry and densitometry equipment discussed in Section 5.1.4, two methods requiring simpler equipment are also suggested in that section. These can be used effectively in small facilities.

### "Normal range of use of equipment"

Most x ray equipment is designed such that it will operate over a very large range of kilovoltage, tube current and exposure time. In certain applications equipment is restricted in its mode of operation to a limited range of these settings. Under such conditions the HARP regulations specify that the equipment need only meet standards over its "normal range of use". This allows the effort of calibration to be directed toward the areas which will have the greatest effect on patient dose and image quality and can considerably reduce the cost of calibrating equipment. At the same time equipment which is only calibrated over part of its possible range of control settings must be clearly marked to that effect and no attempt must be made to use it under conditions in which its performance is not predictable.

## 5.1 Photographic Quality Assurance

In addition to the material included in this section, excellent information on processor quality control techniques is available: (Gray, 1976; Goldman, 1981; Gray, 1982).

### 5.1.1 Storage of film processing chemicals

Chemistry may be obtained in either pre-mixed to "user-to-mix" format. It is important, especially in the case of pre-mixed chemistry that large reserve stocks are not kept on hand but rather supplies are obtained on a frequent and regular basis in order to minimize chemical deterioration as a result of aging.

Chemistry should be stored in an environment in accordance with the manufacturer's specifications. Since chemical fumes can cause deterioration of radiographic film, the chemistry must be kept in a location separate from where film reserves are stored.

### 5.1.2 Preparation of replenishment chemistry

In order to prevent chemical deterioration as a result of oxidation, contamination or precipitation during shelf storage in small facilities (or in satellite processors in large facilities where there is infrequent processing due to specialized workload), only enough replenishment chemistry to meet a normal daily requirement should be prepared at any one time.

In large facilities, a regular replenishment schedule should be established and maintained.

Replenishment chemistry should be prepared in accordance with the manufacturer's specifications.

### 5.1.3 Storage of unprocessed x-ray films

X-ray film must be handled and stored with great care if it is to remain in good condition. Even in the best conditions of storage film will inevitably deteriorate. The acceptable period for which it may be kept before use is known as it "shelf life". Generally, higher speed film has a shorter shelf life than slower film.

When ordering film stock, intake should be adjusted to the rate of use and only stock sufficient to meet demands without a large reserve supply should be kept.

When new film reaches a facility, boxes should be date-stamped so that older stocks may be identified and used first. Film boxes should be stored vertically on shelves in an environment where the temperature is in the region of 10°C (50°F) and does not rise above 18°C (65°F), with relative humidity in the region of 50%. Since dampness and high temperatures have the most damaging effects on photographic materials, rooms with damp floors and walls and rooms subject to sudden temperature changes and condensation are to be avoided. Film should also be stored in an area away from any possibility of exposure by ionizing radiation, and, since chemical fumes may affect film quality, in a location separate from that used to store processing chemistry or other chemical substances.

### 5.1.4 Photographic quality control tests

Frequency: every operational day

Changes in the amount of radiation required to produce a satisfactory image and variation of image contrast frequently result from changes in the photographic processing. Since this is a chemical process, it is very sensitive to changes in the concentration of the chemicals involved, and the time and temperature of processing. For satisfactory results these factors must be regulated carefully and, therefore, tests must be set up to monitor the quality and consistency of photographic processing. Because of the likelihood of drifts, the tests must be carried out on every operational day of the processor and should be repeated even more often if drifts are discovered in an attempt to determine the cause of the problem.

There are three methods which can be used to monitor film processing: sensitometry and densitometry, pre-exposed films, and phantom (step-wedge) imaging. Because the last two have the simplest equipment requirements (but are slightly more time consuming) they may be preferred in very small x-ray facilities.

#### 5.1.4.1 Sensitometry and densitometry

This is the method of choice for all but dental facilities. An instrument called a sensitometer provides variable levels of light which are used to expose the radiographic film in the darkroom. The film is then processed and the optical densities (blackness) of the regions of different light exposure are measured using an instrument known as a densitometer. The results are recorded each day in a log book. The most common types of sensitometer produce a pattern on the film of steps of grey varying from clear to full blackening of the film. The following information should be recorded.

- speed point. This is the optical density under a particular step on the sensitometric image. Generally a step which provides a density of approximately 1.0 above base and fog is chosen. If, for example, the base plus fog density of radiographic film is 0.2, this corresponds to a gross optical density of 1.2). The density of the same step is recorded in the log book each day.

- contrast index. This is generally taken as the difference in density of two steps in the sensitometric image whose densities lie in the straight line portion of the characteristic curve of the film. A convenient point is the difference between the density measurement used for the speed index and the density at a fixed step on the sensitometric image which yields a density approximately one density unit greater than the speed point. Once the steps to be used for the speed and contrast tests have been chosen they should be fixed.

- base plus fog index. This is a measurement of the density of the film where it has not been exposed to light. This provides an assessment of the amount of film fogging. High values (above approximately 0.24 for commonly-used film types) may indicate improper film storage, excessively old film or quality control problems in the manufacture of the film.

Typical log forms for recording the results of these measurements are provided in the Appendix (Chart 2). All three are important indicators of image quality and can be used to reveal not only the existence of problems but in many cases also the reasons for those problems. The main advantages of the sensitometry technique are (a) it is quantitative, ie. it provides numbers which can be monitored over a period of time, (b) it tests the film processing only and isolates it from other possible factors involved in imaging and (c) it provides results instantly which greatly simplifies the tracking-down of processing problems.

Each facility should establish limits of acceptability for variations of the speed point, contrast index and base plus fog and take investigative action when values fall outside those limits.

#### 5.1.4.2 Pre-exposed films (Small facilities*)

This method requires the purchase of a set of films which are pre-exposed to various levels of light so that a range of optical densities will result on the processed film. Processor operation is then monitored using a densitometer or a calibrated optical density reference film (generally available from suppliers of radiographic film or QA equipment) and the same measurements are recorded as in the previous method. One limitation of this method is that in general the type of film supplied will be different from that used routinely with the processor being tested. While this should not normally present a problem it may limit flexibility of the test procedure.

#### 5.1.4.3 Phantom imaging, step-wedge (Small facilities*)

Here, imaging is monitored by producing a radiograph using fixed technique factors of a standard test object or phantom,preferably incorporating a step wedge. The speed and contrast of the resulting film can be compared with previous films either by eye with the help of a calibrated optical density reference film or preferably using a densitometer to observe whether changes in imaging have taken place. If the test object has one or more steps of thickness incorporated in it then an index of contrast can also be determined from the densitometer measurements.

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* i.e. facilities having 1-3 x-ray units and a single processor.

This method is a useful test of overall imaging performance, and because of its simplicity is well-suited for small facilities. However, it is clearly not able to isolate processing performance. If changes are observed using this technique then it is necessary to use more refined tests to determine whether processing or some other factor, eg. the x-ray source or the image receptor, is causing the variation.

### 5.1.5 Developer temperature

Since the quality of processing depends on the temperature of the developer bath it is important to measure this periodically especially if changes in the sensitometric results have been detected. This must be done with a non-mercury thermometer because of the possibility of contamination of developer baths by the mercury. It is convenient and useful to record developer temperature on the same form used for the sensitometry log.

### 5.1.6 Darkroom light leak tests

This is done by exposing a film with the appropriate quantity of x rays or light to obtain a film density of about 1. The exposed, but unprocessed film is then removed from the cassette and left on a darkroom counter where film handling generally takes place for approximately two minutes with one half of the film covered with a material opaque to light. There should be no noticeable difference in density between the two halves of the film when it is processed. A density change indicates light leaks into the darkroom which must be corrected or improper safe light which may be a result of incorrect safe light filter or excessive wattage of the bulb.

### 5.1.7 Repeat film analysis

For various reasons patient radiographs are repeated. In some cases the rate is as high as one film in seven. There are many reasons for repeats: different requirements by radiologists, patient motion, improper positioning, excessive or inadequate optical density, insufficient contrast, equipment malfunction, etc. In all cases, however, the patient receives additional radiation dose per diagnostically-acceptable image produced.

Some repeats are unavoidable and in fact may indicate a high standard of image quality in the facility. On the other hand it is important to minimize avoidable repeats.

The most effective way to discover the reasons for repeat films is to perform a "repeat analysis" and to use the results of such analysis to pinpoint such problems as persistently unreliable automatic exposure termination equipment (phototimers), processing and darkroom difficulties, etc. As well, it is occasionally found that films are discarded and repeated for aesthetic reasons, even though the radiologist, chiropractor, chiropodist or dentist would consider the original film diagnostically acceptable. This problem can be resolved by ensuring good communications between those who produce the radiographs and those who read them. Routine repeat analysis should be part of the quality assurance programme in every facility. In addition to the material provided in these Guidelines more detailed instructions for carrying out repeat analysis are provided in Goldman,1979 and Gray, 1982.

### 5.1.7.1 Setting up a repeat analysis programme

Staff cooperation is vital to the success of a repeat analysis programme. In order to obtain such cooperation it must be made clear that the results of repeat analysis will not be used to initiate disciplinary measures on individual staff. The analysis should be seen as a technique for improving performance of the imaging facility as a whole.

Films which have required retakes should be identified as to the reason for the retake, the x-ray equipment or room used to produce the image, the processor where appropriate and the technologist. Periodically, for example each month the analysis should be carried out using charts such as those given in Tables 5-1 and 5-2 or in the Appendix (Chart 12).

Communication is also essential. It must be clearly established what the diagnostic requirements for the image are. Where these differ among health professionals then this must be recognized and it must be determined whether it is possible to accommodate the preferences of individuals or whether a common standard acceptable to all involved can be agreed upon. Policy regarding standards for image production or for the resolution of any other problems associated with retakes should be established and should be communicated via meetings or a special bulletin board for that purpose.

Retake rates can be analyzed according to the room in which the image is produced or the technologist as in Tables 5-1 and 5-2 or according to the procedure or the reader of the film. Each type of analysis will yield information which can indicate the appropriate action to be taken. Listed below are some of the reasons for retakes and typical recommended action.

**1. Variation in retake rates among radiologists.**

Action: Documentation of radiologists' requirements. Need for improved communication between radiologists and technologists.

**2. Film processing - variation in optical density.**

Action: Correlate, on a daily basis, repeat rates due to density variation with speed index of the processor (see Section 5.1.4). If the pattern of repeat rates due to excessively dark or light films appears to follow the variation in speed index it is good evidence that the stability of film processing is not acceptable.

**3. Variations in x-ray output due to malfunction or miscalibration of equipment.**

Action: If such variations are seen and it is verified that film processing is stable then equipment output problems are a distinct possibility. It should be determined whether the retakes are occurring in manual or automatic exposure termination mode. Records of routine equipment monitoring tests should be consulted and additional tests of reproducibility, linearity and of the phototimer if appropriate should be carried out.

Table 5-1 Retake Analysis By Room And Reason

| | Room # | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Reason | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| Dark | 29 | 37 | 36 | 33 | 33 | 30 | 28 | 31 |
| Light | 45* | 31 | 32 | 32 | 30 | 29 | 31 | 29 |
| Positioning | 20 | 18 | 19 | 19 | 17 | 18 | 19 | 21 |
| Centring | 10 | 11 | 22** | 9 | 9 | 8 | 9 | 10 |
| Motion | 6 | 6 | 7 | 5 | 8 | 6 | 6 | 7 |
| Other | 8 | 6 | 7 | 7 | 6 | 6 | 5 | - |
| Totals | 119 | 111 | 123 | 108 | 107 | 97 | 96 | 98 |

* - Inappropriate technique selection if manual factors are being used
- Phototimer problem if automatic exposure termination used
- Processing if a dedicated processor is used for this room

** Possibility of collimator misalignment

Table 5-2 Retake Analysis By Operator And Reason

| | Technologist # | | | | |
|---|---|---|---|---|---|
| Reason | 1 | 2 | 3 | 4 | 5 |
| Dark | 35 | 31 | 32 | 30 | 43 |
| Light | 32 | 31 | 31 | 34 | 30 |
| Positioning | 20 | 18 | 18 | 30 | 17 |
| Centering | 13 | 12 | 11 | 12 | 11 |
| Motion | 5 | 11* | 4 | 4 | 4 |
| Error | 10 | 4 | 5 | 3 | 3 |
| Other | 5 | 7 | 6 | 6 | 7 |
| Total | 120 | 112 | 107 | 119 | 115 |

* Excessive exposure time (mA too low?)

## 5.2 Patient Entrance Exposure Measurements

Frequency: for medical and chiropractic facilities - 6 months. For dental facilities - 12 months. For chiropodic facilities - 24 months. For all facilities - upon alteration or servicing of the machine which could affect exposures.

It is well known that exposure to x rays increases the probability of induction of certain harmful effects, notably: cancer, birth abnormalities and genetic damage. Although the exact probabilities are not well known it is only good sense to attempt to carry out procedures requiring radiation exposure with the lowest radiation exposure consistent with the benefit of the procedure. In the case of radiological imaging, the benefit generally involves the accuracy of the diagnosis or assessment of disease. The Ontario Ministry of Health X-ray Inspection Branch and other agencies in Canada and the United States have kept records of patient entrance exposures for various diagnostic procedures. This information indicates that, for a particular procedure there is a rather wide variation in the amount of radiation required to produce the image. It is natural to wonder why, when one facility can produce images using a particular level of radiation, another facility will require two or three times that amount of radiation, while a third will use only one-half or one-quarter of the amount (see Section 2.1.7). While it is difficult to state a radiation exposure that is ideal for a particular examination it is reasonable to assume that the wide range of x-ray exposures currently used can be reduced if equipment is operating in an optimum manner and technique is selected properly.

In order to promote this process, Tables 6 and 7 of the Regulations specify maximum allowable exposures for various procedures. These are entrance skin exposures (ESE), excluding backscatter, for a specified view and thickness of body part. Any facility carrying out an examination should be able to operate beneath these levels. The Regulations require that exposures be measured using the appropriate test geometry at intervals no greater than six months for medical and chiropractic facilities, twelve months for dental facilities and twenty-four months for chiropodic facilities. In addition they should be measured whenever servicing or alteration of the machine that might affect exposures has been done. Since these exposure limits are specified for patients of average size it is obvious that for very large patients it will, in some cases, be necessary to exceed these levels.

The exposures listed in the table are defined at the position of the entrance to the patient and are specified without backscatter. They may be measured in several ways but in any case should be recorded on a log form (see for example Appendix, Chart 3).

## Method for measuring exposure

1. The exposure may be measured by placing a dosimeter at the entrance surface to a phantom and making the exposure using manual technique factors or phototiming, whichever is appropriate (see Figure 5-1a). This measured exposure will include backscatter which can then be eliminated by multiplying the measured exposure by the appropriate factor for the kVp and field size used. These correction factors are given in Table 5-3. The phantom used for this purpose should represent typical x-ray attenuation for the appropriate body part.

2. For procedures normally carried out with manual technique selection, the dosimeter can be placed at the position of the entrance to a patient of specified thickness without a patient or phantom in place and the measurement can be made in air as in Figure 5-1b. An insignificant amount of backscatter will then contribute to the measurement and the result can be compared directly with Table 6 or 7 of the Regulations.

3. The dosimeter can be placed at a position between the x-ray source and the phantom where it receives negligible backscatter. The exposure can be made using manual technique selection or phototiming and the measured exposure reading can be corrected for the inverse square law effect to describe the exposure that would result at the entrance surface to the phantom. This is done as shown in Figure 5-2.

## Table 5-3 Factors To Remove Effects Of Backscattered Radiation From Measured X-Ray Exposures*

| kVp | HVL | (Size of X-Ray Field At Entrance Surface To Patient) | | | |
|---|---|---|---|---|---|
| | | 5x5 cm | 10x10 cm | 15x15 | 30x30 cm |
| 60 | 1.1 | .88 | .85 | .83 | .82 |
| | 1.5 | .86 | .83 | .81 | .79 |
| | 1.9 | .85 | .80 | .79 | .78 |
| | 2.3 | .83 | .79 | .78 | .76 |
| 75 | 1.4 | .86 | .82 | .81 | .81 |
| | 1.8 | .83 | .79 | .79 | .78 |
| | 2.2 | .82 | .78 | .76 | .76 |
| | 2.7 | .81 | .76 | .75 | .74 |
| 90 | 1.7 | .85 | .80 | .80 | .79 |
| | 2.2 | .84 | .78 | .76 | .75 |
| | 2.6 | .83 | .76 | .74 | .73 |
| | 3.3 | .81 | .75 | .72 | .71 |
| 100 | 2.0 | .83 | .79 | .76 | .76 |
| | 2.6 | .83 | .77 | .75 | .73 |
| | 3.1 | .81 | .75 | .72 | .70 |
| | 3.8 | .80 | .74 | .70 | .68 |
| Higher kVp | | .80 | .74 | .70 | .68 |

Multiply exposure (when measured in the presence of backscatter) by factor in the appropriate row and column to obtain exposure excluding backscatter.

* Adapted from R.M. Harrison, Physics in Medicine and Biology Volume 27, pages 1465-1474, 1982.

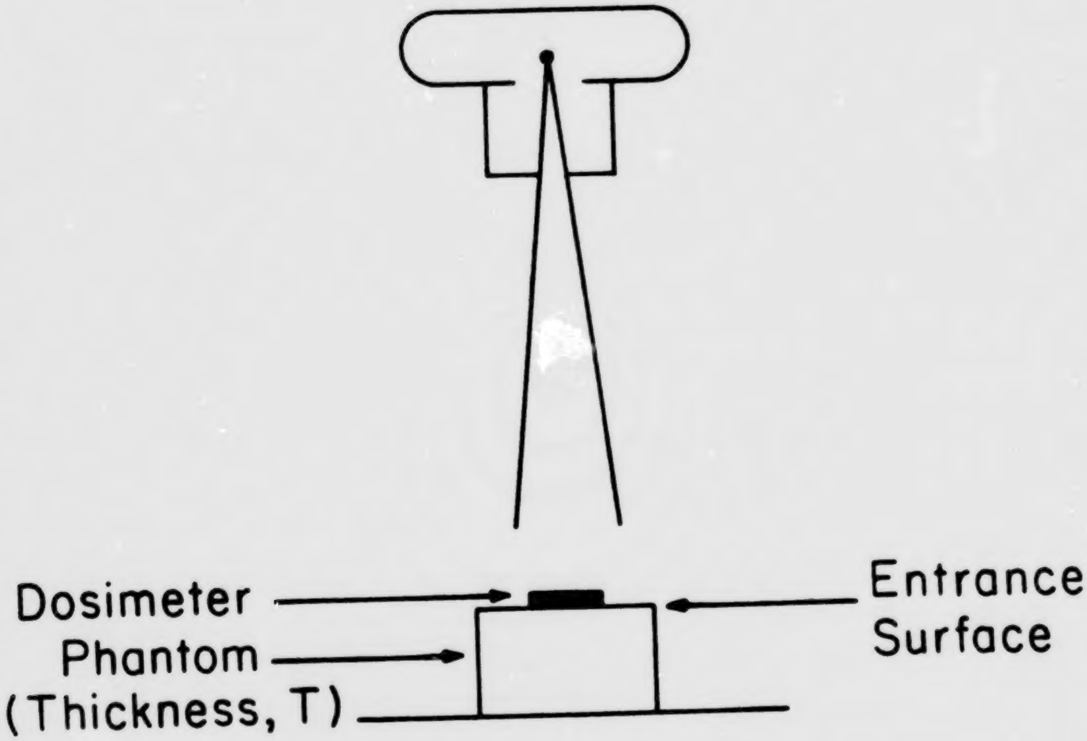
Dosimeter
Phantom
(Thickness, T)
Entrance Surface

Figure 5-1(a) Direct Measurement Of Entrance Exposure (includes backscatter)

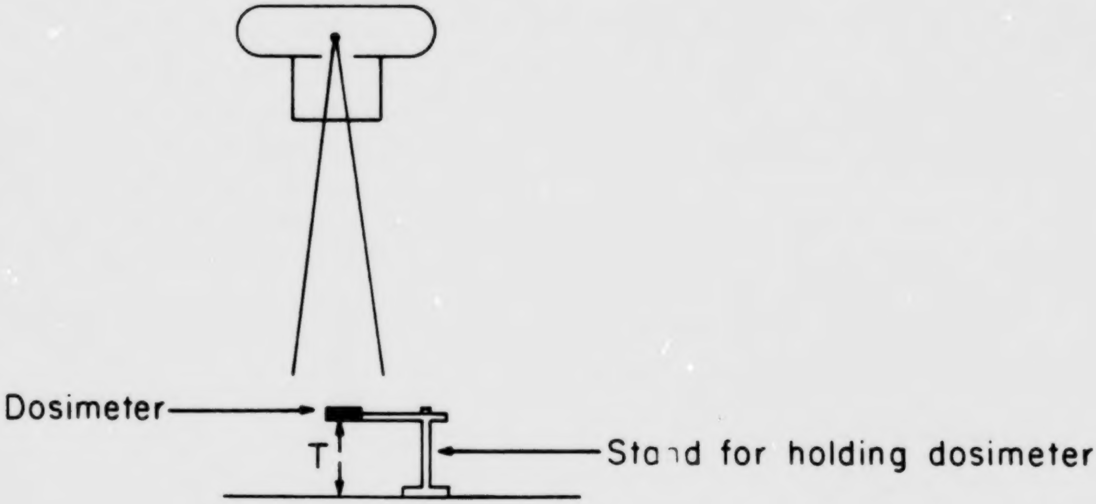
Dosimeter
T
Stand for holding dosimeter

Figure 5-1(b) **Measurement of Exposure in Air At Entrance Surface To Patient (no backscatter)**

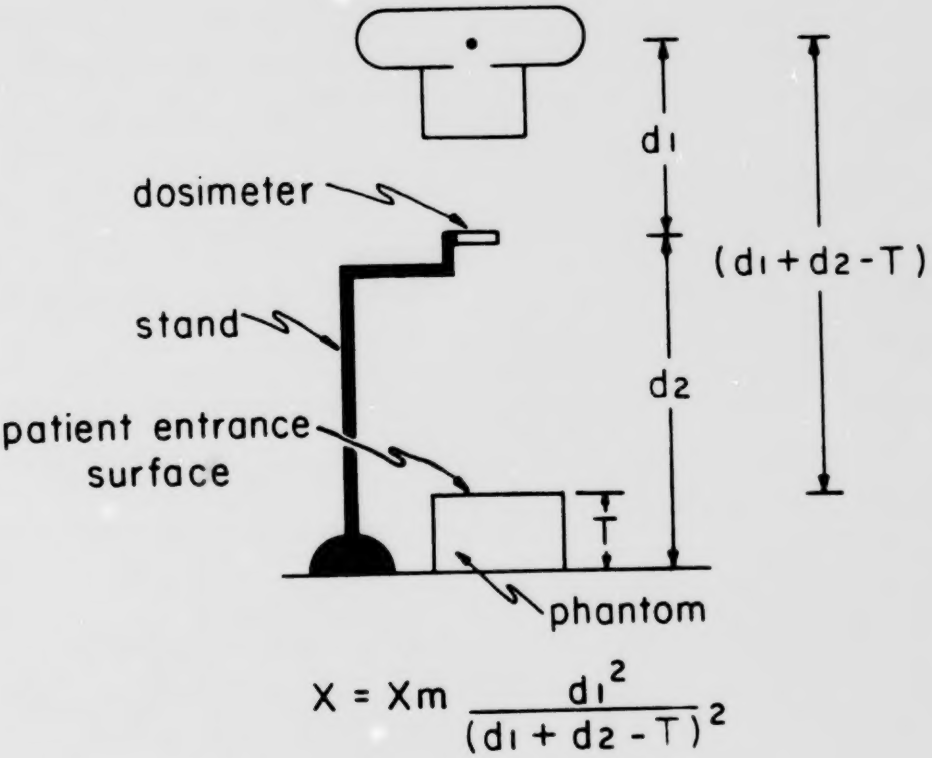
dosimeter
stand
patient entrance surface
phantom
$d_1$
$d_2$
$(d_1+d_2-T)$
T
$X = Xm \frac{d_1^2}{(d_1+d_2-T)^2}$

**Figure 5-2 Determination Of Entrance Exposure Excluding Backscatter Via Inverse Square Law Technique.**

If exposure Xm is measured with dosimeter located at $d_1$ from focal spot, then exposure X at patient entrance (excluding backscatter) is given by:

$$X = Xm \frac{d_1^2}{(d_1+d_2-T)^2}$$

(Phantom required only if automatic exposure technique is used.)

If exposures are found to be higher than the levels specified in the Regulations remedial action will be required. The common causes of high exposures are summarized in Table 5-4.

### Table 5-4 Causes Of High Patient Exposure

1. Use of an inadequately sensitive image receptor resulting from inappropriate selection of film screen combination, or aging of screens causing reduced light emission.

2. Inadequate sensitivity of film processing resulting from degradation of processing chemistry, reduction of processing time or temperature.

3. Selection of too low a kilovoltage resulting in inadequate penetration of the body part.

4. Inadequate filtration in the x-ray beam

5. Materials in the post-patient x-ray beam (eg tabletop, cassette front) which excessively attenuate the image-forming beam.

6. Use of too high a grid ratio for the examination.

## 5.3 Collimation

Frequency: for medical and chiropractic facilities 6 months. For other facilities 12 months. For all facilities upon servicing of the tubehead or collimation assembly.

It is important that the extent of the radiation beam be closely matched to the region of the patient required to be imaged. In x-ray units which use collimators, the area of irradiation is generally indicated by a light beam localizer. The Regulations require that collimation accuracy be tested at the intervals stated above and in addition upon servicing of the tube head or collimation assembly. This can be done quickly and easily using one of the test devices commercially available. Alternatively a simple test device can be made. A typical arrangement for this is shown in Figure 5-3 and makes use of nine metallic objects such as eight pennies and a dime mounted on a sheet of rigid material such as cardboard or thin plastic. To test the collimation, this device can be placed on the patient table or equivalent such that the centre mark is aligned with the indicator which shows the centre of the light field. The collimator plates in each dimension are adjusted so that the light field coincides with the meeting points of the objects on each edge. An exposure is performed, a test cassette placed either directly below the device or in the bucky tray and a test film is produced. The images of the objects will indicate the position of the light field and the area of darkening on the film will indicate the actual radiation field. The results of this test should be recorded (see for example Appendix, Chart 4) and can then easily be compared to the standard expressed in Section 14 of the Regulations i.e. that the light localizer field and radiation fields are not misaligned by greater than 2% of the distance between the target and the test cassette.

A similar test device can be easily produced to evaluate beam limitation in equipment used with a single size of image receptor and a fixed x-ray target to image receptor distance that must comply with Section 15 of the Regulations.

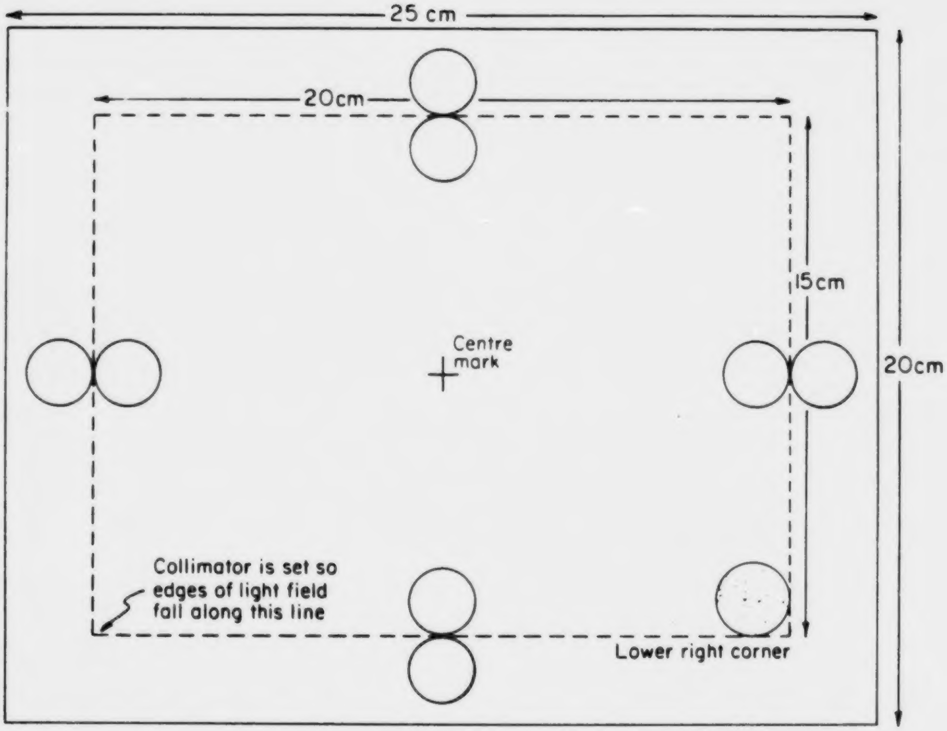
25 cm
20cm
15cm
20cm
Centre mark
Collimator is set so edges of light field fall along this line
Lower right corner

Figure 5-3 A Simple Tool For Checking Accuracy Of Collimator Alignment

## 5.4 Half-Value Layer

Frequency: for medical and chiropractic
facilities 6 months. For other facilities
12 months.

As discussed in Section 3.3, the penetrating power of the beam affects both patient dose and image contrast. It depends largely on the kilovoltage and total filtration of the x-ray beam. For this reason standards for kilovoltage accuracy are specified in Sections 12-(2)-(b), 17-(3) and 19-(1)-(c) of the Regulations. These must be met by all equipment over the normal range of use for that equipment. The Regulations do not specify the required frequency of tests of kilovoltage accuracy. This should be determined by the facility based on past performance of the equipment and repairs which might alter kVp calibration. The Regulations do specify that the penetrating power of the x-ray beam be assessed at regular frequencies (given above) by measurement of the half-value layer (H.V.L.).

Measurement of half-value layer provides a simple test to determine whether the combination of kilovoltage and added filtration in the x-ray beam provides adequate penetrating power. Minimum standards for half-value layer at each operating kilovoltage are specified in Table 8 of the Regulations.

The half-value layer is defined in the Regulations as the thickness of a specified material, that attenuates the x-ray beam (under conditions that minimize the measurement of scattered radiation) to one-half of its value in the absence of that material. For the purposes of the Regulations, Type 1100 aluminum (the commercially-pure form of aluminum), should be used in measurements as the "specified material".

### 5.4.1 Measurement of half value layer

To measure H.V.L., the x-ray machine is set at a nominal kilovoltage value which is initially assumed to be accurate. The half-value layer is then determined. If it is not at least as great as the value specified in Table 8 of the Regulations then the penetrating power of the beam is insufficient. The amount of added filtration in the beam should then be checked and if it is inadequate should be increased (see Section 3.3.4). If the amount of additional filtration is found to be acceptable then it is likely that the kilovoltage is miscalibrated and is too low. The kilovoltage should then be checked independently using one of the available methods described in Section 5.6 and should be corrected if necessary.

#### Equipment required

- X-ray dosimeter.
- 2 sheets of lead approximately 3 mm (1/8") thick of dimensions approximately 10 cm x 10 cm, one with a hole approximately 1 cm in diameter drilled in its centre. For rigidity the lead sheet can be glued to an aluminum sheet with a slightly larger hole drilled in its centre. When this is done the plate should be used with the aluminum facing away from the x-ray tube.
- A stand or other convenient means of supporting the lead plate.

- Several sheets of Type 1100 aluminum of dimensions somewhat greater than the hole in the lead sheet. 5 or 6 sheets 1 mm thick and 1 sheet 0.5 mm thick are generally sufficient. For techniques performed below 50 kVp an assortment of aluminum sheets of thickness 0.1 mm are required.
- Sheets of 1 or 2 cycle semi-logarithmic graph paper. Linear graph paper can be used, however, the determination of HVL with semilog graph paper is much easier once its use has been learned.

## Arrangement

The recommended setup for vertical x-ray beams is shown in Figure 5-4. The dosimeter is generally placed on top of the lead sheet which has no hole in it. The x-ray tube is positioned above the dosimeter at the largest practical distance, eg. 100 cm such that the central ray of the x-ray beam strikes the centre of the dosimeter. The lead sheet with the hole is positioned approximately halfway between the x-ray tube focal spot and the dosimeter such that the centre of the x-ray beam passes through the hole. The light localizer of the x-ray collimator is generally sufficiently accurate for this purpose. For horizontal beams an analagous arrangment can be used.

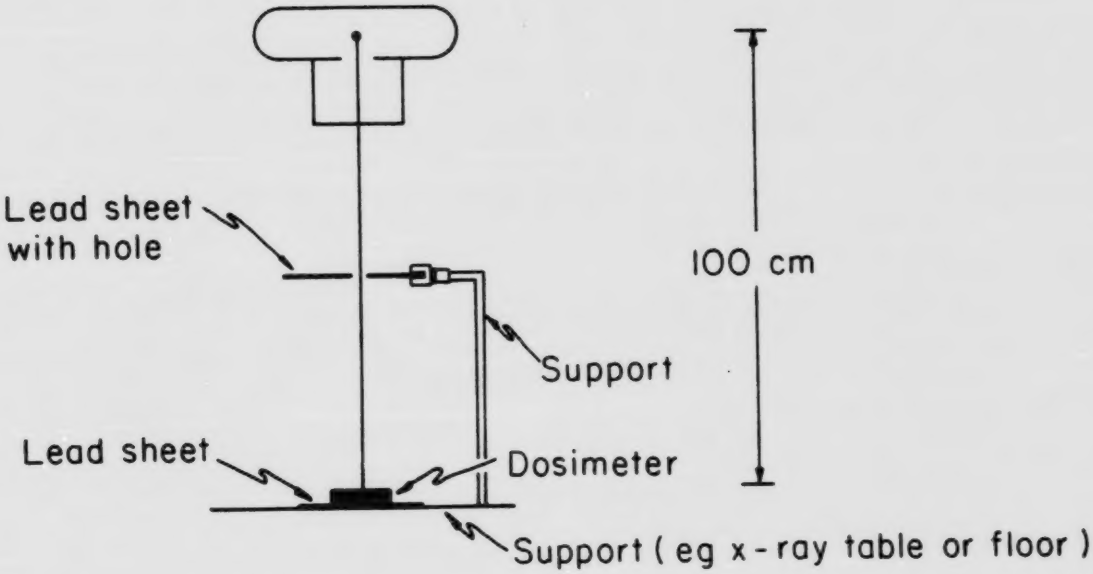
Lead sheet with hole
100 cm
Support
Lead sheet
Dosimeter
Support ( eg x - ray table or floor )

**Figure 5-4 Arrangment for Half-Value Layer (H.V.L)**

## Measurement

1. Select a kilovoltage at which H.V.L. is to be measured. Two or three values in the "Normal Range of Use for the Equipment" should be sufficient.

2. Select a mAs value sufficient to provide a reliable dosimeter reading without imposing excessive heat loading on the x-ray tube. Select the focal spot size which is normally used for imaging.

3. Make two or three exposure measurements with these factors and record these values.

4. Calculate the average of these readings and record it.

5. Place a sheet of aluminum (say 1 mm for a general radiographic beam) over the hole in the lead sheet. Make another exposure with the same technique.

6. Divide this result by the value calculated in step 4.

7. Plot the result against the thickness of added aluminum on a sheet of semi-logarithmic graph paper. (The value for "0" added aluminum is always equal to "1").

8. Repeat steps 5,6,7 for additional sheets of aluminum always plotting the result against the total thickness of aluminum sheets resting on the lead plate.

9. Continue until the aluminum has reduced the reading to less than one half of its original value.

This process is illustrated in Figure 5-5. The measured points on this graph are joined with a smooth curve and the value of added aluminum required to reduce the fraction of the original exposure to 0.5 (the half value layer) is recorded (see for example Appendix, Charts 5, 5a and 5b).

Example: 80 kVp, 3 phase x-ray unit

| Thickness of Aluminum Placed on lead sheet | | Dosimeter Reading (mR) | Relative Transmission |
|---|---|---|---|
| 0 mm | | 127 | |
| 0 | | 128 | |
| 0 | | 129 | |
| | Average | 128 | 1.0 |
| 1 | | 92 | 0.72 |
| 2 | | 72 | 0.56 |
| 3 | | 56 | 0.44 |
| 4 | | 44 | 0.34 |
| 5 | | 36 | 0.28 |

The HVL of this beam is 2.4 mm of aluminum.

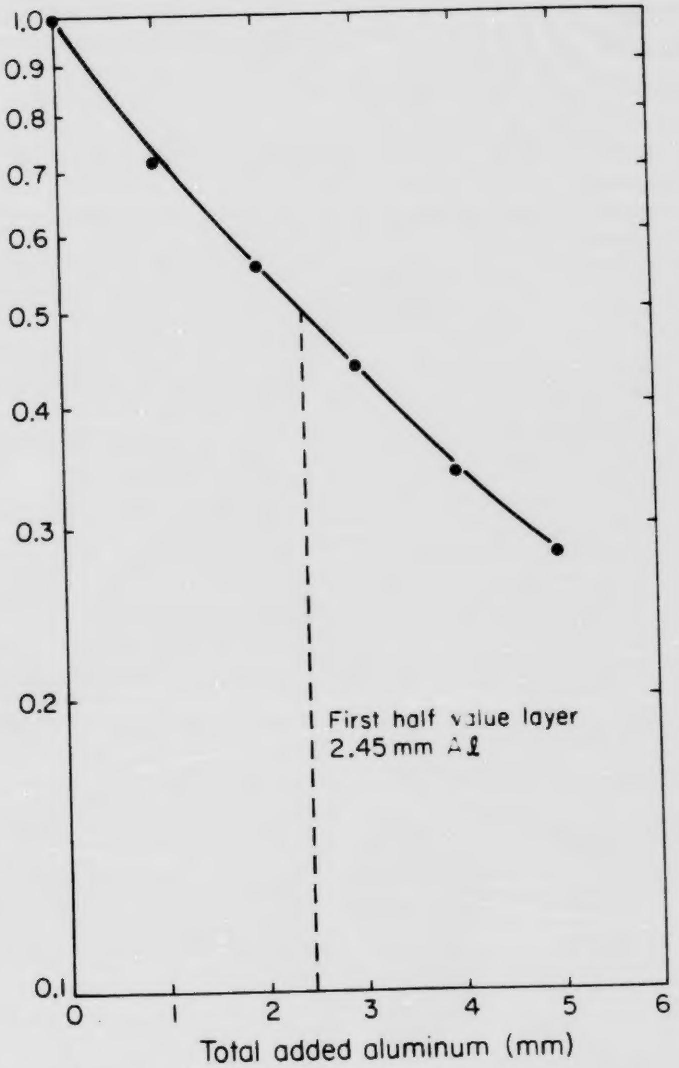

Figure 5-5 Measurement of Half-Value Layer (H.V.L)

### 5.4.1.1 Half-Value Layer of Fluoroscopic Systems

For fluoroscopic systems with manually-controllable technique factors, the procedure is identical to that for radiographic systems described above. Kilovoltage and tube current are held at fixed values during the set of exposure measurements and of course the arrangement of apparatus is adapted to suit the geometry: i.e. undertable or overtable x-ray tube. A sheet of copper may be placed over the intensifier to prevent its exposure to direct radiation.

The measurements should be done with the dosimeter in the "exposure rate" mode. The generator should be allowed to reach stable operating conditions before the measured exposure rate is recorded.

For systems with automatically-controlled factors, it is necessary to stabilize those factors during the measurement procedure. If this cannot be done by overriding the automatic control, another approach is suggested here.

1. Tape a sheet of copper over the front face of the image intensifier.

2. Tape five 1 mm thick sheets of type 1100 aluminum over this sheet. The thickness of the copper should be such that the combined copper and aluminum drive the automatic exposure control to typical values for operation of the fluoroscopy machine.

3. Adjust the fluoroscopic collimators as for typical patient imaging.

4. Mount the dosimeter about midway between the focal spot and image intensifier and at least 10 cm above the table (to avoid measurement of backscatter radiation).

5. Measure the exposure rate under fluoroscopy. This is the value for 0 mm aluminum.

6. Transfer 1 mm of aluminum from the image intensifier to the tabletop beneath the dosimeter and record the exposure rate under fluoroscopy as the "value for 1 mm Al".

7. Repeat this process until the exposure rate falls to less than half of the "0 mm" value. The total amount of aluminum in the beam is always maintained at 5 mm so that the technique factors should remain approximately constant.

8. Record kV and mA and plot exposure measurements versus thickness of aluminum between the x-ray tube and dosimeter to obtain the HVL.

**Note:** Because this method requires a relatively large radiation field area (to ensure that the automatic brightness control operates under typical conditions) and lead cannot be used, some scattered radiation will be measured and measured HVL may be higher than the true value which would be obtained under "zero-scatter" conditions.

## 5.5 Standards Of Functioning (Reproducibility, Accuracy, Linearity)

In order to perform high quality radiological imaging at the minimum dose to the patient it is important that the equipment perform in a reliable and predictable manner. Many of the Regulations are designed to address this point. These regulations set standards for the **reproducibility, accuracy** and

**predictability** of the output of x-ray machines. Since these terms may be confusing to the reader they will be defined here.

### 5.5.1 Reproducibility

Reproducibility is a measure of how closely the same result occurs when an x-ray exposure is repeated many times. For example, if the variable of interest is exposure time then reproducibility would be tested by making several "identical" exposures and determining how much these varied from a constant value. An established method for doing this is in terms of the "coefficient of variation" which is defined in Section 1 of the Regulations.

The coefficient of variation is evaluated as follows.

1. Some number, n, of measurements is made.

2. Their average is calculated.

3. The difference between each measurement and the average value is obtained.

4. These differences are squared.

5. The square values are totalled (ie n numbers are added together).

6. This sum is then divided by (n-1) to obtain the "expected variance".

7. The square root of this value is obtained (the standard deviation).

8. This is divided by the average of the n original measurements.

**Example**: In a test of radiation output 10 measurements were obtained. These are shown in the second column with their sum and average (mean) below.

| Measurement # | Value | Difference from Mean | Square of Difference |
|---|---|---|---|
| 1 | 237 mR | -3.5 | 12.25 |
| 2 | 250 | 9.5 | 90.25 |
| 3 | 242 | 1.5 | 2.25 |
| 4 | 240 | -0.5 | 0.25 |
| 5 | 244 | 3.5 | 12.25 |
| 6 | 248 | 7.5 | 56.25 |
| 7 | 230 | -10.5 | 110.25 |
| 8 | 235 | -5.5 | 30.25 |
| 9 | 241 | 0.5 | 0.25 |
| 10 | 238 | -2.5 | 6.25 |
| Total | 2405 | | 320.5 |

Average (mean) = 2405/10 =240.5

For measurement #1 the difference from the mean is 237-240.5 = -3.5. The difference squared is (-3.5) X (-3.5) = 12.25

Expected variance = 320.5/(10-1)= 35.6

Coefficient of variation = $\sqrt{35.6} \div 240.5 = 0.025$

Although this procedure seems complicated it is the most mathematically correct way to measure reproducibility and is the most effective way to state the intention of a regulation specifying reproducibility. Generally, especially in the performance of the quality assurance programme, it should not be necessary either to make a large number of test exposures or to calculate the coefficient of variation. The performance of as few as three exposures should reveal whether there are reproducibility problems. If problems are detected then a complete test including calculation of the coefficient of variation for a few selected machine settings should be done.

### 5.5.2 Accuracy

Accuracy is a measure of how close the actual machine performance is to the stated value. For example, in the case of timer accuracy the generator control will have a set of nominal time settings. The actual exposure time may be completely reproducible but may still not be accurate, ie may not be the same value as the nominal time setting. In general, accuracy is less critical than reproducibility, however, it is still important that the output of the equipment be reasonably close to the stated value.

> **Example:** At a timer setting of 100 ms the actual exposure time (averaged over a few measurements to eliminate concerns about reproducibility) is 108 ms. The inaccuracy is +8ms. The percentage inaccuracy is 8/100 = 8%.

### 5.5.3 Linearity

It is often necessary in x-ray imaging to adjust technique factors to obtain the correct film density. To facilitate this it is important that the effect of varying the factors is predictable. For example, the amount of x rays produced is assumed to be proportional to the product of the time setting and the tube current ie. to the mAs selection. For the same value of mAs, regardless of the individual time and mA settings it is assumed by the operator that the same amount of x rays are produced, ie. for a given kilovoltage, the x-ray output in milliroentgens per mAs (mR/mAs) should be independent of the mA or time settings. This is because the amount of x rays depends linearly on both the mA and time. This also implies that a given fractional increase in mA or time settings will result in the same fractional increase in radiation output. In the Regulations this sort of predictability is specified in terms of the linearity of equipment performance.

Linearity between any two settings on the x-ray generator is tested by measuring x-ray output at each setting and comparing the values of mR/mAs obtained. Ideally at any fixed kVp, they should be identical. The standard for linearity in the HARP Regulations is that the difference between two measurements (ignoring minus signs) must be no greater than 0.1 times the sum of the measurements. In practice, this permits about 20% nonlinearity.

## 5.6 Measurement Of Kilovoltage Accuracy

There are two principal methods for measuring kilovoltage accuracy: indirect and direct.

### 5.6.1 Indirect measurement of kilovoltage

Indirect techniques do not require connection to the high voltage circuit of the x-ray machine but instead rely on measurements of the penetrating power of the x-ray beam. These devices contain a sensor which is placed in the x-ray beam and exposed to radiation at the nominal kilovoltage which is to be tested. Generally, devices of this type rely on a set of x-ray filter materials. When the penetration of radiation through these filter materials is carefully measured the kilovoltage can be determined quite accurately, especially at kilovoltages above 40. A variety of such test devices ranging in cost, sophistication and ease of use are available. These include instruments which measure kilovoltage only or combine kilovoltage measurement with determination of other factors such as half value layer, x-ray waveform exposure, linearity etc.

### 5.6.2 Direct measurement of kilovoltage

The direct or "invasive" method requires connection of a voltage-measuring device directly to the secondary (high voltage portion) of the power supply that feeds the x-ray tube. As such it is generally a more accurate method of measuring kilovoltage, especially for mammography. The devices used to perform this measurement are known generically as voltage dividers or "bleeders". The peak kilovoltage can be read on a meter, determined from the display on an oscilloscope connected to the voltage divider or, in some test devices, calculated by a microcomputer and displayed digitally. The latter two methods have the advantage of being capable of displaying the kilovoltage waveform as well as the actual value of peak kilovoltage. Measurement of kilovoltage by the direct method requires connection and disconnection of cables which handle over 100,000 volts. Unless proper precautions are taken voltages can remain on these cables even when power to the equipment has been shut off. Direct measurement of kilovoltage should only be done by personnel who are properly trained in measurement techniques and in safety procedures for working with high voltage equipment. As well, improper reconnection of terminals can severely damage x-ray equipment.

## 5.7 Measurement Of mA Or mAs Linearity

1. A dosimeter is placed at a convenient distance from the x-ray source.

2. The kilovoltage for the test is selected and a fixed exposure time short enough that the test will not apply an undue heat loading to the tube is selected.

3. Exposures are then made at each tube current which is within the normal range of use of the machine.

3a. In the case of equipment where only mAs (rather than mA and time)can be selected exposures are made at each mAs setting within the normal range of use of the unit.

4. The exposure is measured and the selected value of mAs is recorded.

5. The exposure values are then divided by the mAs data and the results are recorded.

For each two mA or mAs stations of interest (i.e. adjacent currents or mAs values varying by at least a factor of 2 from one another) the test is applied. The difference of mR per mAs is compared to the sum for the two measurements and this difference must be less than 1/10th of the sum for compliance.

**Example:** 80 kVp, .055 s, 1 m focal spot to dosimeter

| mA Setting | "mAs" | Exposure Measured (mR) | mR/"mAs" | Test Result |
|---|---|---|---|---|
| 25S * | 1.25 | 21 | 16.8 | |
| | | | | - .08 |
| 50S | 2.5 | 36 | 14.4 | |
| | | | | - .07 |
| 100S | 5 | 63 | 12.6 | |
| | | | | - .004 |
| 200S | 10 | 125 | 12.5 | |
| | | | | - .05 |
| 300S | 15 | 170 | 11.3 | |
| | | | | - .06 |
| 300L | 15 | 190 | 12.7 | |
| | | | | - .008 |
| 400L | 20 | 250 | 12.5 | |
| | | | | - .25 ! |
| 800L | 40 | 297 | 7.43 | |
| | | | | - .08 |
| 1000L | 50 | 316 | 6.32 | |

* S indicates small focal spot

In this example mA linearity was tested for both focal spots. Some additional settings were included (i.e. mA values differing by less than a factor of two) to cover the normal range of operation of this unit. The break in linearity between the 400L and 800L stations with acceptable linearity from 25mA to 400 mA and between 800 mA and 1000 mA indicates a calibration problem. Technique adjustment based on mAs values, between the 400 and 800 mA stations would yield unpredictable film densities and remedial action should be taken.

Typical forms for recording mA or mAs linearity test results are given in the Appendix, Charts 8 and 8a.

## 5.8 Tests Of Automatic Exposure Termination And Back Up Timer frequency: every 6 months

### 5.8.1 Automatic exposure termination (Phototiming)

Much of modern radiography is performed with equipment that automatically terminates x-ray exposure when a predetermined amount of radiation has reached a sensor on the exit side of the patient. When properly operating, automatic exposure termination systems can improve the reliability of obtaining the desired optical density of patient exposures by compensating for variations in patient size and x-ray opacity. On the other hand, these systems can mask problems with the x-ray machine by compensating for changes in machine output due to miscalibration or malfunction. As well, if the automatic exposure termination system itself is not functioning properly this will lead to inadequate image quality.

### 5.8.1.1 Tests of automatic exposure termination system

Equipment required -

- Variable thickness phantom - this can consist of a set of slabs of phantom material (sheets of aluminum or preferably a plastic such as plexiglas) or a tank of water which can be filled to varying levels.

Method -

1. A typical kilovoltage used for the equipment is selected. It may be necessary to perform this test at a variety of kilovoltages depending upon the use of the equipment.

2. Using the film and screen in the bucky which is normally used for the equipment, images are made for a variety of phantom thicknesses encompassing the range of patient absorption encountered on the equipment. If plastic or water are used as the phantom materials their range of thicknesses should be about the same as the range of patient thicknesses. If aluminum is used thicknesses of up to approximately 35 mm (1.5 inches) will be required.

3. Films produced with automatic exposure termination should yield approximately constant optical density regardless of phantom thickness. Over the working range of phantom thicknesses the optical densities of all phantom images should be within ±0.1 of each other.

4. This test should be performed for the different combinations of exposure timing sensors used on the equipment and, if tube current is varied, at several mA stations as well.

### 5.8.2 Backup timer test

Equipment required -

- Any instrument that will allow measurement of exposure time.

Method -

1. Select kilovoltage and tube current values typically used on the equipment.

2. Place a sheet of lead approximately 30 cm x 30 cm and 5 mm (1/4" thick) on the x-ray table.

3. Centre the x-ray beam upon the lead sheet and adjust collimators so that the field lies within the boundaries of the lead sheet.

4. Place the exposure timing device above the lead sheet.

5. Make an exposure using automatic exposure termination and read the exposure time. With the lead in place this will be equal to the maximum value allowed by the automatic system (backup time). The equipment must comply with Section 12-(1) of the Regulations. For kilovoltages less than 50 the backup system must terminate the exposure at 2,000 milliampere-seconds per exposure or less. For kilovoltages of 50 or more, termination must occur at or before one of the following limits (at the manufacturer's option):

a. 600 milliampere-seconds per exposure

b. 60 kilowatt-seconds per exposure

## 5.9. Other timer tests

### 5.9.1 Timer accuracy

Intervals for testing the accuracy of the exposure timer are not specified in the requirements of the mandatory quality assurance programme although standards for timer accuracy itself are included in the Regulations (12-(2)-(d), 17-(4)-(c) and 19-(1)-(b)). It has been found that if the timer operates at all its accuracy rarely drifts and the timer, therefore, requires less attention than the kV or mA calibration. The timer accuracy should be tested whenever deemed necessary by the R.P.O. to ensure that it complies with the Regulations over its normal range of use.

#### 5.9.1.1 Measurement of timer accuracy

There are several methods available for measuring exposure time to verify compliance with the Regulations. The least expensive methods involve the use of "spinning tops". For pulsed x-ray systems the tops can be manually driven while multi-phase power supply x-ray systems require a motor driven disc rotating at constant speed. These devices are radiographed and the exposure time is determined by analysis of the number of dark spots on the film in the case of single phase systems or the angle subtended by the blackened area in the case of multi-phase x-ray systems.

More sophisticated devices are available and are recommended in larger facilities where many measurements must be made. These include digital x-ray exposure timers which automatically provide direct readout of exposure time and radiation sensors which are used with an oscilloscope to display the x-ray waveform directly. In the latter case additional useful information which may indicate faults in equipment can be obtained from observation of the x-ray waveform.

Timer reproducibility can be asessed with the same equipment used to measure timer accuracy, however if x-ray output reproducibility meets the requirements of 12-(2)-(a), 17-(4)-(a) or 19-(1)-(a) the test should not be necessary.

### 5.9.2 Phototimer sensitivity adjustment

This control allows for changing the operating point of the exposure termination device to allow for changes in density on the film or to compensate temporarily for processing variations. With a constant-thickness phantom in place and a dosimeter placed at the entrance surface of the phantom, images should be produced at each setting of the phototimer sensitivity control. At the same time the entrance exposure should be measured. For each type of film used with the equipment, a table of phototimer setting versus percentage change in radiation exposure and the numerical difference in optical density (with respect to the normal phototimer setting) should be given. The table should be posted near the x-ray control console to allow the technologist to make corrections in film density when necessary. This test of the calibration in the phototimer sensitivity settings should be done upon acceptance of the equipment and periodically afterwards.

### 5.9.3 Minimum exposure time

The automatic exposure termination device and the x-ray generator have some minimum time at which an exposure can be terminated reliably. If exposures are carried out with high speed image receptors and at high tube current, the time actually required to obtain a film of adequate density may be less than can be accommodated by the x-ray system. Films will then tend to be dark and/or fluctuating in density because the termination system is always operating at the minimum point in its range. Minimum exposure time on an automatic system can be determined using a method like that in Section 5.8.1 but with gradual reduction in the thickness of the phantom while measuring the exposure time with an appropriate instrument. As the phantom thickness is reduced, eventually it will be found that the exposure time does not decrease because the minimum has been reached. At this point, images will start to become overexposed. If actual patient examinations for this thickness range must be done on the equipment, the most practical solution is to reduce the tube current so that exposure time will be lengthened to times within the effective operating range of the termination device. By reducing x-ray tube current it may in some cases also be possible to use a smaller focal spot which will provide improved spatial resolution.

## 5.10 Measurement Of Fluoroscopic Exposure Rates

### 5.10.1 Under-table x-ray tube

For under-table x-ray tubes the standard way of measuring entrance exposure rate is to place a dosimeter on the examination table and to place a phantom on suitable supports such that it lies directly above the dosimeter. If a water phantom is used, a polyethylene bucket with a uniform flat bottom is convenient as a container. A scale in centimetres of water depth can be marked on the side of the bucket for convenient filling to the appropriate levels. It is important that the water depth be accurate as a small difference can have a large effect on exposure rate in automatic exposure rate systems. Also, for all fluoroscopic exposure rate measurements, the distance between the x-ray tube and intensifier should be fixed at normal working position and this distance should be recorded and used for all subsequent testing.

The dosimeter selected for measuring exposure rates on automatic brightness controlled systems must be such that it has minimal effect on the radiation output. Therefore, it should be as transparent as possible to the x-ray beam. As well it should preferably be placed in a position where its presence does not influence the sensor of the automatic exposure rate control of the fluoroscopy system. If this is not possible then on some equipment fluoroscopy can be done without the dosimeter in place to establish the operating values of mA and kVp under automatic exposure control conditions. These values can then be set and the fluoroscopy machine operated under manual exposure control with a dosimeter in place and the exposure rate measured in this way.

### 5.10.1.1 Automatic brightness control

The fluoroscopic automatic brightness control is designed to provide an image of acceptable brightness level during the fluoroscopic procedure regardless of patient thickness or opacity. This is done by a feedback system which monitors the brightness of the fluoroscopic image and controls the x-ray generator to adjust kilovoltage, mA or both. The simplest test of automatic brightness control operation is to measure the exposure at a fixed point in space as various thicknesses of phantom material are successively placed in the x-ray beam. A graph of exposure rate versus phantom thickness should show that the rate increases with thickness until the maximum allowable exposure rate is reached at which it remains constant even though thickness is increased. A graph showing typical performance is shown in Figure 5-6.

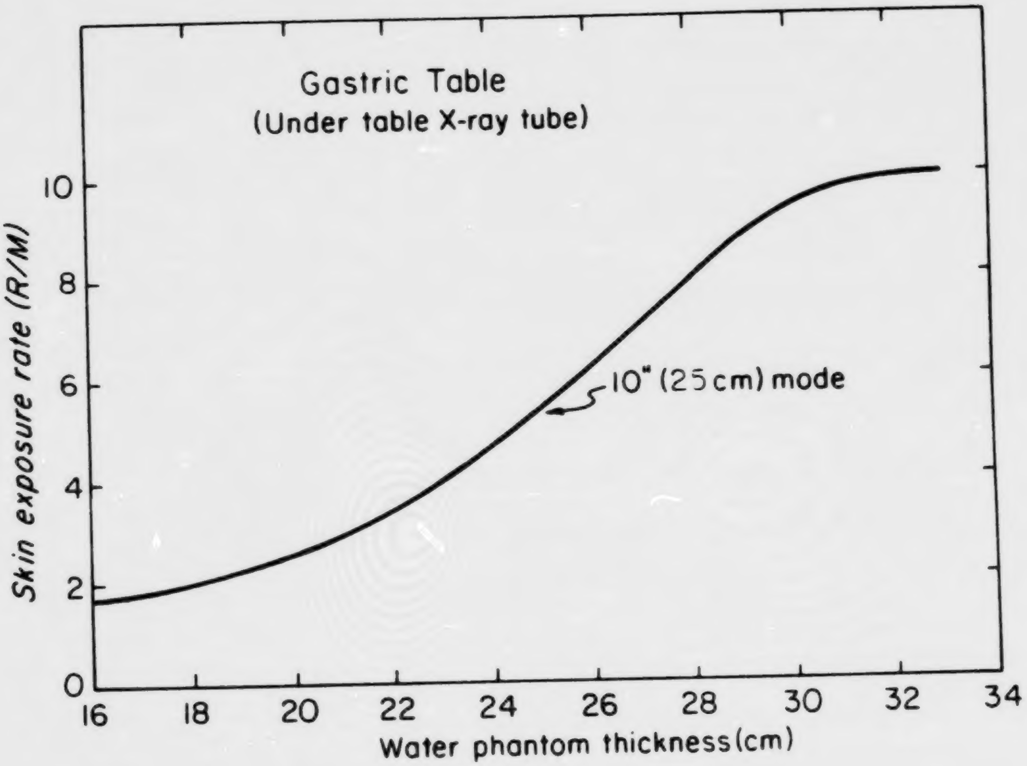

**Figure 5-6** Typical Performance of Fluoroscopic Automatic Brightness Control

### Procedure

For under-table x-ray tubes the dosimeter is placed on the fluoroscopic table surrounded by suitable supports such that a phantom can be placed above the dosimeter without damaging it. Two or three centimeters of phantom material are then placed over the dosimeter, the image intensifier is kept at fixed height above the table and an exposure is made under automatic brightness control conditions. The exposure rate is read and recorded. This procedure is repeated for the entire range of x-ray attenuation likely to be encountered on patients for this equipment. A graph of exposure rate versus phantom thickness is recorded.

### Evaluation of Results

Test results should show that:

1. Exposure rate increases with phantom thickness until the maximum allowable value is attained.
2. The brightness of the fluoroscopic image remains approximately constant independent of the phantom thickness.

If these results are not observed the service engineer should be requested to examine the equipment.

### 5.10.1.2 Average exposure rate

Limits for the entrance exposure to a 20 cm water phantom are given in Sections 16-(4)-(b) of the Regulations for ZnCdS intensifiers and in 16-(5)-(b) for CsI intensifiers as 5 R/min and 2.5 R/min respectively. These limits include backscatter and are based on the use of a 23 cm (9") diameter intensifier.

Measurement is performed in exactly the same manner as described in 5.10.1.1 with 20 cm of water in the container.

### 5.10.1.3 Maximum entrance exposure rate

The maximum exposure rate can be measured by simply removing the water phantom and replacing it with a sheet of lead which completely intercepts and attenuates the x-ray beam. A thickness of approximately 1/4" (6 mm) lead equivalent is appropriate for this purpose. The dosimeter is placed on the x-ray tube side of this lead sheet. The automatic exposure control will then drive the exposure variables up to their maximum attainable levels and the exposure rate can be measured.

### 5.10.1.4 Manual exposure control

For equipment where exposure rate is controlled by manual selection of kVp and mA measurement of exposure rate is somewhat simpler. Measurements are performed under the conditions of kVp and mA that are normally used for a patient of 20 cm thickness. The phantom and dosimeter are positioned as described above. Maximum exposure rates are determined by adjusting both mA and kVp to their maximum values. The lead sheet is not required.

## 5.10.2 Overhead x-ray tube fluoroscopy equipment

### 5.10.2.1 Average exposure rates

Here the phantom is placed directly on the examination table and the dosimeter is supported just above its top surface. One way of doing this for water phantoms is to rest the dosimeter in a thin-walled plastic container floating on the surface of the water. (The dosimeter must not be allowed to get wet!)

### 5.10.2.2 Maximum entrance exposure rates

To measure maximum exposure rates for overtable x-ray tube fluoroscopy equipment, the phantom is generally left in place to maintain the dosimeter in the proper position at the entrance surface. The sheet of lead is placed beneath the phantom on the table top to drive the automatic exposure control to its maximum value.

### 5.10.2.3 Automatic brightness control

The procedure is similar to that of Section 5.10.1.1 ,however, the dosimeter is placed at a fixed height above the phantom so that it does not move as phantom thickness is varied. This effectively separates the change in exposure rate due to the automatic brightness control from that due to inverse square law effect if the dosimeter rested on the phantom.

### 5.10.3 Manual exposure control

For manual exposure control equipment measurements can be made in a similar manner. The phantom should still be used because it provides the backscatter exposure which should be included in the fluoroscopic exposure rate measurements. For manual operation, however,it is not necessary to use the lead sheet because the equipment can be driven to its maximum value simply by increasing kVp and mA settings to their upper limits.

Typical forms for recording fluoroscopic exposure rate measurements are given in the Appendix, Chart 6.

## 5.11 Measurement Of Fluoroscopic Resolution

There are several stages in the fluoroscopic imaging system at which losses in spatial resolution can occur. Of course the normal radiographic factors such as focal spot size and geometric magnification factor between the patient and the imaging system will influence resolution. Assuming that these have been optimized in the selection of equipment and choice of technique resolution will be affected by the following additional factors:

1. Original quality of the image intensifier
2. Field size of the image intensifier (magnification mode)
3. Electronic focus of the intensifier
4. Focussing of optics coupling the intensifier to subsequent video or photographic cameras
5. Electronic focussing of the video camera
6. Electronic focussing of the video monitor

The adjustment of most of these factors requires the experience and skill of a qualified service engineer or medical physicist and normally should not be undertaken without special training. Nevertheless the resolution of the imaging system can be easily monitored by the quality control technologist. All that is required is a resolution test pattern which is commercially available from the suppliers of radiological test equipment. Such patterns generally consist of alternate radiopaque and radiolucent regions spaced at regular intervals. Bar patterns, star patterns and mesh patterns are commonly available.

In order to evaluate the resolution of the imaging chain the test pattern is placed as close as possible to the input surface of the image intensifier. It is often convenient to mount it on the front face of the intensifier using tape. The pattern is then imaged fluoroscopically using a low kilovoltage.

When only automatic brightness control is available it may be necessary to place a sheet of x-ray absorbing material such as aluminum or copper of uniform thickness on the examination table to avoid overexposure to the imaging system.

The image is viewed in the normal way, through the mirror or lens viewer of the intensifier or on the video monitor where the imaging system incorporates a video chain. The resolution is measured either in terms of the finest mesh which can be resolved in the viewed image or, in the case of bar or star patterns, as the maximum number of line pairs per millimeter which can just be resolved.

If this measurement is made on each fluoroscopic system when it is newly installed and has just been adjusted by the manufacturer then a baseline value of performance can be obtained. This can then be used to assess the system during future routine quality control measurements and also to compare various system within the facility. Typical expected resolution values can be obtained from the manufacturer of the imaging system.

Since the resolution will depend on the field size (magnification mode) of the intensifier the measurement should be made for all field sizes available.

## Notes

1. When video systems are used it is recommended that the pattern be attached to the image intensifier input such that the bar or mesh lines are at 45° to the raster lines of the video image.
2. It is important that the resolution measurement be made in a reproducible manner with all variables set identically from measurement to measurement. Since this is a subjective measurement resolution values may vary with the observer performing the test.

3. When a decrease in resolution is noted, the service technologist should be requested to evaluate the cause of resolution degradation and to adjust the equipment if possible.

4. It is important that the test pattern be as close as possible to the input of the image intensifier so that blurring due to magnification and focal spot size is excluded from the measurement.

## 5.12 Testing The Limit Timer

Fluoroscopic equipment is required to be fitted with a timer which gives an audible indication after five minutes of fluoroscopy have elapsed or terminates exposure after this time. The former scheme is much preferred since it avoids possible interruption of a procedure at a critical time.

The purpose of the timer is to make the operator aware of the amount of fluoroscopy which has been done and to encourage keeping fluoroscopy times as short as is feasible.

The simplest way to verify proper operation of this device is to monitor a fluoroscopic observation while keeping track of fluoroscopic time with a stop watch.

## 5.13 Tomographic Tests

The regulation requires that the quality assurance programme includes evaluation of the following tomographic parameters every six months;

1. fulcrum accuracy,
2. thickness of cut, and,
3. mechanical stability.

Inexpensive tomographic test tools which may be easily manufactured in the facility will allow in-house testing of all three parameters.

### 5.13.1 Fulcrum Accuracy, Thickness of Cut

A simple phantom (Fig. 5-7) may be constructed, using a block of wood, wire mesh, paper clips or short lengths of heavier wire, a thin lead sheet, and lead numbers, to assure that the tomographic cut level and thickness are correct and that the image sharpness is optimal. With this phantom only one exposure is required for the test.

Alternatively, a four-inch by four-inch sheet of lead with a 1/16 inch countersunk pinhole in the centre (Fig. 5-8) may be used to assess these parameters. This method, however, may require a number of exposures to determine the actual cut level if the first exposure shows an inaccuracy. In addition, it will not actually measure the thickness of the cut, but will indicate a change in the thickness in cases where the tomographic program selected is not completed.

### Simple Phantom for Assessing Fulcrum Accuracy and Thickness of Cut

1. Cut a triangular-shaped piece from a two-inch by four-inch piece of wood. The angle of the triangle should represent the exposure angle most frequently used. (Alternatively more than one phantom may be made representing each of the exposure angles used in the facility.)
2. Attach a copper window screen of #40 mesh to the angled surface of the wood block.

3. Attach paper clips straightened out, to the screen, at selected cut levels normally used in the facility.

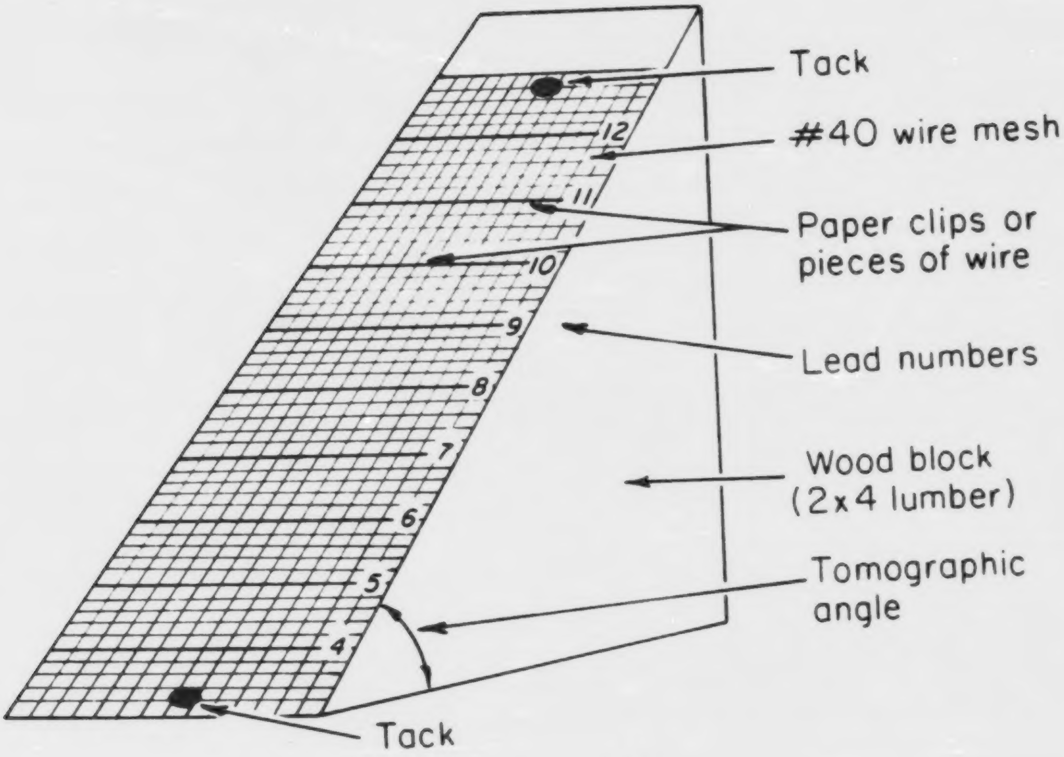
Tack
#40 wire mesh
Paper clips or pieces of wire
Lead numbers
Wood block (2x4 lumber)
Tomographic angle
Tack
12
11
10
9
8
7
6
5
4

Figure 5-7 Simple Tomographic Phantom

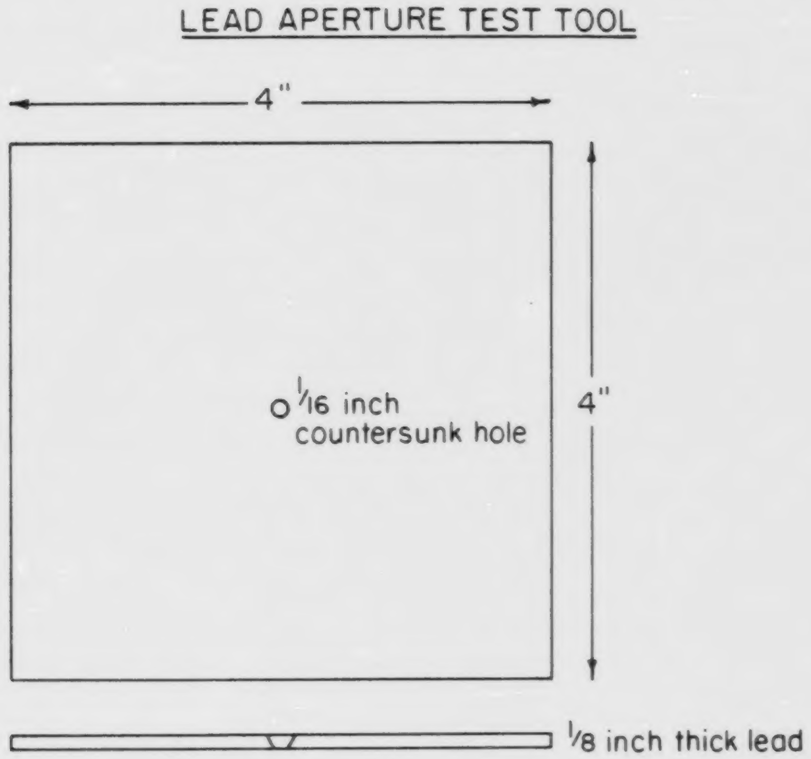
LEAD APERTURE TEST TOOL
4"
4"
1/16 inch countersunk hole
1/8 inch thick lead

Figure 5-8 Lead Aperture Phantom

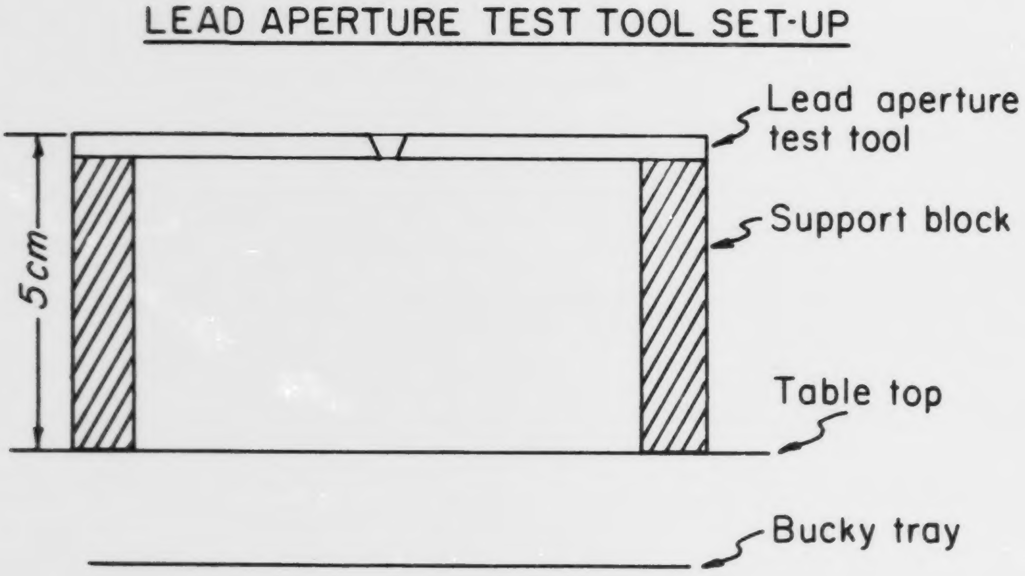
LEAD APERTURE TEST TOOL SET-UP
Lead aperture test tool
Support block
5cm
Table top
Bucky tray

Figure 5-9 Setup For Mechanical Stability Test

4. Attach lead numbers to indicate the cut levels.

5. Attach a thin lead sheet such as found in an old cassette to the base of the wood block.

### 5.13.1.2 Procedure for Testing Fulcrum Accuracy and Thickness of Cut

The tomographic test phantom is placed on the table top (at a 45 degree angle to the tube-film motion if a linear system is being evaluated) and centred to the x-ray beam. The fulcrum level is set to the level of one of the paper clip markers. The amplitude setting most commonly used is selected. With a loaded cassette in the tray an exposure is made of the Phantom using the lowest mA available, a low kVp (50) and the exposure time appropriate for the amplitude setting. The radiograph is then processed and evaluated.

A properly functioning tomography unit will produce one sharp area located near the indicated plane of cut with an increase in blurring as the distance from the plane of the cut increases. In addition, the sharp area will be at the indicated level if the fulcrum is accurate.

Eratic motion of the tomographic unit will produce several areas that appear to be sharp at different levels with blurred areas in between.

### 5.13.1.3 Procedure to test Fulcrum Accuracy using the Lead Aperture Plate

The lead aperture plate is positioned 5 cm above the table top using a stable spacing device (e.g. Fig. 5-9) with the hole centred to the central ray of the x-ray field. A loaded cassette is placed in the tray and the x-ray beam is collimated to a size 3 inches by 3 inches. The most commonly used tomographic motion, exposure angle and sweep speed is selected. A cut The cut level is set at 5 cm at the fulcrum. An exposure is made, the film is processed and the radiograph is evaluated. If the fulcrum is accurate the resultant film should show a single round pinhole density. If there is an extended trace showing, the fulcrum is inaccurate. To determine the degree of inaccuracy, the procedure is repeated changing the fulcrum level up or down. The lead aperture plate must remain in the same position 5 cm above the table top. This method may necessitate a number of radiographs being taken to determine the actual fulcrum level.

### 5.13.2 Mechanical Stability

Testing the mechanical stability of the tomographic unit can be easily done using a four-inch by four-inch by 1/8 inch sheet of lead with a 1/16 inch countersunk pinhole in the centre. The test procedure will also enable one to assess whether the exposure angle has been maintained during linear tomography. In multidirectional tomography this test can indicate that either the exposure angle or the thickness of cut has changed, as a result of an incomplete program, but it will not identify in either case to what degree.

#### 5.13.2.1 Procedure to test the Mechanical Stability

The lead aperture plate is positioned on the table top as for testing fulcrum accuracy. Collimation and technical factors are also set the same. The cut level of 6-10 cm is selected at the fulcrum. The cut level once selected should be kept as a standard reference. A low kVp is selected as well as a time appropriate for the amplitude setting. An exposure is made, the film is processed and the radiograph is evaluated.

The tomographic image of the hole in the aperture plate is a reproduction of the trajectory of the x-ray tube during the tomographic exposure. The density of the image over the reproduced trajectory should appear uniform. Variations of the uniformity of the image density are indicative of mechanical problems in the tomographic drive mechanism. For single phase equipment the density pattern will appear as a series of pulsating dots because of the pulsating nature of the waveform.

The resultant radiograph obtained in this test procedure may also be used to determine the actual exposure angle used in linear tomography.

### 5.13.3 Calculation of Exposure Half-Angle used in Linear Tomography

Measure, with a centimeter ruler, the length of the tracing on the radiograph. Construct a triangle with this measurement as the base (see Fig. 5-10). Calculate (C/2b) mathematically. The exposure half-angle can be calculated as arctan (C/2b) or else can be read from Table 5-5.

b Distance from apex to base of reconstructed triangle.
Measured from image of tomographic test tool scale.
C Measured with centimeter ruler on test film.

## Table 5-5 Calculation Of Tomographic Exposure Half-Angle

| C/2b | Exposure Half Angle |
|---|---|
| .11 | 6 |
| .14 | 8 |
| .18 | 10 |
| .21 | 12 |
| .25 | 14 |
| .29 | 16 |
| .33 | 18 |
| .36 | 20 |
| .40 | 22 |
| .45 | 24 |
| .49 | 26 |
| .53 | 28 |
| .58 | 30 |
| .63 | 32 |
| .68 | 34 |
| .73 | 36 |
| .78 | 38 |
| .84 | 40 |
| .90 | 42 |
| .97 | 44 |
| 1.04 | 46 |
| 1.11 | 48 |
| 1.19 | 50 |
| 1.28 | 52 |
| 1.38 | 54 |
| 1.48 | 56 |
| 1.60 | 58 |
| 1.73 | 60 |

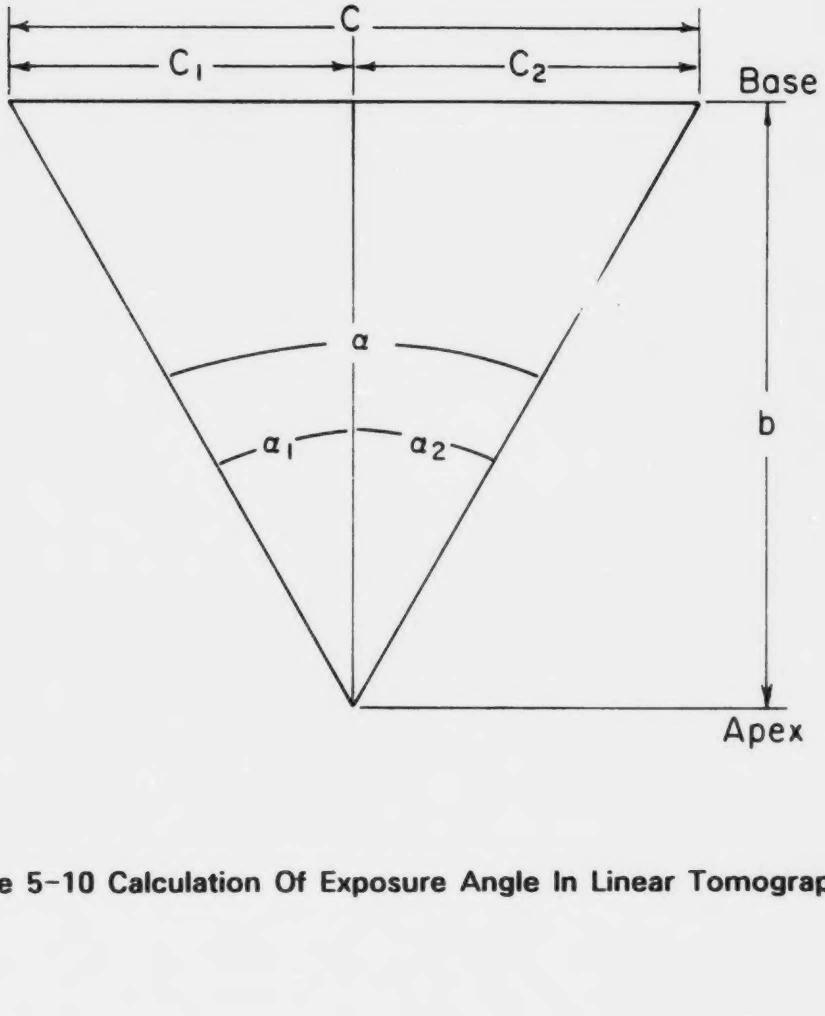
C
C1
C2
Base
α
α1
α2
b
Apex

Figure 5-10 Calculation Of Exposure Angle In Linear Tomography

# 6 ACCEPTANCE TESTING

In its broadest sense a quality assurance program in diagnostic radiology should begin with the selection of equipment.

Before purchase, the imaging requirements for a particular installation must be translated into a set of technical specifications for the equipment. The equipment satisfying these technical specifications is then selected and installed. Following installation and before clinical use, the equipment must be subjected to a series of acceptance tests in order to confirm that the equipment actually performs at the level described in the technical specifications agreed upon by the manufacturer and purchaser and to demonstrate compliance with the Federal Radiation Emitting Devices Act (in the case of new equipment) or the Ontario Healing Arts Radiation Protection Act (in the case of newly installed used equipment).

Acceptance testing may be considered as a more extensive quality control testing of the equipment and would include all the tests of the routine quality control program plus a number of others depending on the specific use of the equipment (Hendee 1977, 1979, 1979a; McLemore 1981; Gray 1982) to ensure that the standards under the appropriate legislation (the RED Act and its regulations or the HARP Act and its regulations) were met. During the acceptance testing phase, performance data are compiled that serve as a comparative "baseline" standard for similar data collected subsequently during routine quality control procedures. After the equipment has satisfied all the acceptance test procedures, it is released for clinical use. It is advisable that for the first few weeks of clinical use, the performance of the equipment is monitored closely to confirm that no problems arise.

Acceptance testing should be carried out under the direction of a suitably qualified individual such as a medical physicist, a radiological technologist or engineer with special training in measurement of radiation and image quality. Written evidence of such tests indicating compliance with the Radiation Emitting Devices Act (Canada) for new equipment or the Healing Arts Radiation Protection Act for newly-installed used equipment and the regulations made thereunder must be supplied by the radiation protection officer of the facility to the Director of X-Ray Safety within 60 days of installation.

Included below are sample checklists for acceptance testing of facilities in accordance with the regulations under the Radiation Emitting Devices Act and the Healing Arts Radiation Protection Act.

## RADIATION EMITTING DEVICES ACT - COMPLIANCE CHECKLIST*

Date:________________

Institution:____________________

mailing address:

Contact person:

Equipment:

Manufacturer:

Model number:

Serial number:

RED Act requirements

3. Information supplied by manufacturer

a. installation instructions provided

complete maintenance instructions on site

b. i) maximum line current

ii) focal spot size

method of measurement:

iii) installation and assembly instructions line voltage specs.

---

*This list is a summary only. For exact wording refer to the Act and Regulations.

line impedance specs.

iv) battery minimum charge specs.

4. Labelling and markings on equipment
    - a. Control Panel
        - i) A) Unauthorized use label
            - B) Hazardous emission in operation label
        - ii) Radiation warning sign - triangle
        - iii) Identification label
            - A) name of manufacturer
            - B) model designation
            - C) serial number
            - D) date of manufacture
            - E) country of manufacture
    - b. X-Ray tube housing
        - i) x-ray tube insert label
            - A) name of manufacturer
            - B) model designation
            - C) serial number
            - D) date of insert in housing
            - E) country of manufacture
        - ii) minimum beam filtration of housing
    - c. X-Ray tube
        - i) Focal spot mark
        - ii) Cathode and Anode marked
    - d. Collimator
        - total permanent filtration

5. (1) Every machine shall have:

- a) all labels secure
- b) all meters and controls clearly labelled
- c) X-Ray tube secure and aligned correctly
- d) no drift or vibration in tube during exposure
- e) Two tubes
    - i) only one may be energized at one time
    - ii)
        - A) Visible indication on each housing
        - B) Control panel indication of which tube ready

(2)

- a) line voltage compensator
- b) if line out of range
    - i) warning or
    - ii) interlock
- c) Control Panel
    - i) Warning lights
        - A) Power on (ready for exposure)
        - B) X-Ray on
    - ii) meters on adjustable factors
        - A) kVp
        - B) mA
        - C) time
    - iii) marks or labels if not adjustable
    - iv) battery charge indicator

d) Exposure switch initiate and terminate

e) Audible signal at end of exposure

f) Filters

  i) permanently fixed

  ii) HVL no less than Table I (of RED Regs.)

g) filter interlock switches

  if i) permanent inherent less than .5 mm Al

    ii) designed to be used with additional filtration

h) Emergency stop and terminate on remote control device

6. (1) Exposure switch

  a) requires continuous pressure for X-rays

  b) footswitch doesn't expose if overturned

  c) cannot reach outside shielded area (general equip)

  d) Mobile equip at least 3 metres long

(2) Timing device

  a) presettable - any one of:

    i) time

    ii) mAs

    iii) number of pulses

  b) terminate by operator

  c) resets to zero at termination

  d) no exposure possible at off position

(3) Collimators provide same degree of shielding as tube housing

**RADIOGRAPHIC MACHINES**

7. Automatic exposure control
    - a) indication when AEC selected
    - b) if greater than 50 kVp, minimum exposure time
        - i) field emission tubes - 2 pulses
        - ii) others - 1/60 sec or 5 mAs whichever is greater
    - c) maximum exposure limit
        - i) less than 50 kVp maximum exposure is 2000 mAs
        - ii) greater than 50 kVp
            - A) maximum exposure is 600 mAs
            - B) maximum heat units = 60 kWs per exposure
    - d) Backup timer
        - i) Tomo 10.0 sec
        - ii) all others 3.0 sec
    - e) If limits hit
        - i) visible warning
        - ii) manual reset before re-exposure

8. (1) Stationary general equipment
    - a) beam limiting device
    - b) light localizer 100 lux at 1m
    - c) light field accuracy
        - i) misalignment not greater than 2% FFD
        - ii) size accurate to within 2% FFD
    - d) indication of perpendicularity
    - e) method to centre within 2%

(2) Beam Limiting device (for 8.(1)(a))

- a) stepless adjustment

  not less than 5 cm x 5 cm at 100cm

- b) either

  - i) automatic adjustment within 5 sec

    - A) to field size of image receptor
    - B) to preselected portion of image receptor

  or ii) limit exposure if beam 3% greater than receptor

- c) allow adjustment to less than image receptor size

(3) Override of positive beam limitation

- a) key switch
- b) automatic reset when image receptor changed
- c) warning light if override in effect

9. Mobile

- a) Beam limitation

  stepless

  min size 5 cm x 5 cm at 1m FFD

- b) Light localizer

  100 lux

- c) Light accuracy

  less than 2% FFD error

  size indicator accurate to within 2% at 1m

10. Fixed size installation

- a) centre of field aligned to within 2% FFD
- b) X-Ray field confined to receptor

**MAMMOGRAPHY**

11.(1) a) beam limitation
    - i) less than 2% FFD extended to chest wall
    - ii) does not extend beyond any other edge of image receptor

  b) image receptor supporting device-transmitted exposure < 0.1 mR

(2) Removable cones and apertures labelled clearly
  - a) image receptor size
  - b) FFD

12. Mammography on general machines

meet section 11 when setup

13. **SPOT FILM DEVICES**
  - a) Positive field limitation
  - b) manual adjustment to smaller field size
  - c) misalignment less than 3% FFD

14. Others
  - a) Beamlimiting device centred within 2% FFD
  - b) Field doesn't overextend by 2% on any side

15. **FLUOROSCOPIC EQUIPMENT**
  - a) Image Intensifier
    - i) shielding
      - A) beamstop for any FFD
      - B) scatter and primary 'sufficiently' attenuated
      - C) Interlock if beamstop not in place
      - D) attenuates to less than 2 mR/hr behind receptor

    - ii) if shielding removable, interlocked
  - b) .25mm equiv drapes for scatter
  - c) interlock if no image receptor on stationary equip
  - d) exposure switch
    - i) continuous pressure required
    - ii) terminates at any time
  - e) audible signal
    - i) preset timer up to 5 min
    - ii) sounds after preset time until reset
  - f) positive field limitation

    within 3% FFD
  - g) meters or indicators for mA and kVp
  - h) limit FSD
    - i) mobile - 30 cm
    - ii) stationary - 38 cm
    - iii) special applications - 20 cm

16. Cinefluorographic

    meters indicating mA and kVp

17. High level control
    - a) special means to activate
    - b) continuous manual activation
    - c) audible signal

18. Limitation on material between patient and receptor

(1) at 100 kVp , HVL = 2.7 mm equivalent thickness

Fixed table 1.0 mm Al

Moving table 1.5 mm Al max

Cradle 2.0 mm Al max

Front panel of image receptor 1.0 mm Al

(2) Total excluding grid 3.5 mm Al max

19. Standards of functioning for all machines

a) reproducibility of exposure

time > .1 sec on 10 exposures

i) coefficient of variation < .05

ii) all measurements within 15% of mean

b) kVp accuracy

i) within 5% of indicated

ii) line voltage compensation for 7% line variation

c) timer

i) can be set to 5 mAs or 1/60 sec whichever is greater

ii) accurate to within 1/60 sec or 7% " " "

iii) reproducible as in a) at all settings

i) variation < .05

ii) within 15% of mean

d) mA linearity

difference between any two adjacent mA stations

$$x1 - x2 <= .1\ (x1 + x2)$$

e) mammographic beam stop transmission

i) mammographic mode, ii) min FFD, iii) max kVp,mAs

< .1 mR per exposure

f) fluoroscopic maximum rate

- i) at shortest FSD with no ABC
  - A) 5 R/min except during recording
  - B) 10 R/min in high level mode
- ii) with ABC at shortest FSD
  - A) less than 10 R/ min
  - B) if high level control, 5 R/min on normal
    10 R/min on high

g) leakage radiation

less than .1% of beam exposure rate at 1m from housing

h) for mammography 5cm from housing less than 2 mR/hr

i) under non-exposure conditions, less than 2 mR/hr at 5cm from housing

j) no emission from other components over 2 mR/hr at 5cm

k) transmission through IA less than 2 mR/hr 10 cm behind image receptor for 1 R/min patient entrance exposure rate.

# HARP ACT COMPLIANCE CHECKLIST*

Date:________________

Institution:____________________

mailing address:

Contact person:

Telephone:

Equipment:

Manufacturer:

Model number:

Serial number:

Registered owner:

Radiation Safety Officer:

Telephone:

Plans registered

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*This list is a summary only. For exact wording please refer to the Act and Regulations.

## Harp Requirements

3. 1) Room shielded

5) Walls and doors shielded

6) Doors fitted with self closers

if accessible to public, "Warning X-Rays" sign

7) Film storage protected

8. 1) On Control Panel or at Exposure Switch

A) "Unauthorized use" label

B) "Hazardous emission in operation" label

2) a) all control, meters clearly identified

b) X-ray tube secure and well aligned

c) Tube housing stable when locked

d) Warning lights or other indicators

i) "Ready for exposure"

ii) "Exposure"

e) Technique indication before exposure

f) kVp indicated before exposure if AEC

g) Battery charge indication

h) Only one tube can be energized

i) Visible indication of which tube selected

3) a) exposure switch and timer controlled by operator

b) filters

i) in collimator or tube port

ii) intercept entire beam

iii) HVL acceptable (Table 8)

9. 1) Exposure switch

a) cannot be used outside shielded area (general equip)

b) on mobile equip, at least 3 meters in length

3) Continuous pressure required for x-rays (deadman switch)

4) On serial changer mode allows termination at any time

5) Footswitch prevents exposure if overturned

10.1) Timer terminates at

a) Preset time interval

b) Preset mAs

c) Preset number of pulses

except with automatic exposure control

2) Automatic exposure control terminates at preset radiation exposure

3) Timing device

a) Resets to zero at termination of exposure

b) Does not permit radiation at "off" position

11. Leakage of Beam limiting device < 100 mR/hr at 1m

12.1) Automatic Exposure Control

a) Indication of selection

b) Backup timer

i) if less than 50 kVp, at 2000 mAs

ii) if > 50 kVp

A) maximum 600 mAs

or B) maximum 60 kW-s per exposure

c) Warning when backup condition has been reached

2) Every Machine (except mammography,dental,chiropody)

a) over normal range of operation

i) ten exposures at same settings < 0.08 coefficient of variation

ii) each of the ten exposures within 10% of mean

b) At all settings of kVp, kVp accuracy within +- 8%

c) Timer must operate at greatest of 1/30 sec or 5mAs

d) Timer must be accurate to within +- 10% over normal range

e) At all settings in d), a)i) must be met

12-4) mR/mAs in normal range of use

Difference/Sum :

within 10% at any two adjacent "mA" settings

5) within 10% at any two "mAs" settings differing by factor of two

13.1) Housing leakage at 1m < 100 mR/hr

14.1) General and Mobile Collimator

a) stepless adjustment of field size

b) min size 5cm x 5cm at 1m

c) field always within receptor

2) b) dimensions of field can be adjusted smaller than receptor

3) light field

a) misalignment less than 2% FFD

b) indicators of field size accurate to within 3% of FFD

15. General machines with fixed FFD and receptor size

a) centre aligned to within 2% FFD

b) x-ray field contained within receptor

16. **FLUOROSCOPIC MACHINES**

1) must have

a) image intensification system

i)+ii) Shielding

A) intercepts complete primary beam

B) interlocked to prevent x-rays if no shielding is in place to intercept the useful beam

- b) if Stationary -- interlock if no image receptor is in place
- c) audible signal
  - i) Preset time warning (max 5 min)
  - ii) sounds when x-rays produced beyond preset time

  or Timer
  - iii) Terminates exposure after preset time (max 5 min) and
  - iv) must be reset to zero to restart
- d) indication of current in mA
- e) limits target to skin distance
  - i) mobile -- 25 cm
  - ii) stationary -- 38 cm
  - iii) special -- 20 cm
- f) beam limiting device
  - i) adjustable to less than receptor size
  - ii) aligns field to within image receptor
- g) Shielding of at least .25 mm Pb for scatter from patient for stationary machines

4) Exposure rate limits at shortest Target Skin Distance (ZnCdS)
- a) Max 12.5 R/min
- b) Avg 5 R/min for 20 cm H2O

5) Exposure rate limits at shortest FSD (CsI)
- a) Max 10 R/min
- b) 2.5 R/min for 20 cm H2O

6) With High level control, 5 a) and 4 a) don't apply

7) High Level control (if higher than rates in 4 and 5)
- a) must be activated by separate control
- b) must have audible warning signal

17.1) **MAMMOGRAPHY**

a) beam limitation

i) less than 2% FFD extended to chest wall

ii) does not extend beyond any other edge of image receptor

b) image receptor support -

for maximum exposure conditions, less than .1mR transmitted

2) Removable cones labelled clearly

a) image receptor size

b) FFD

3) KVp accurate +-1 kV up to 35

+-4 % above 35

4) a) For any setting Coefficient of Variation < .08

b) Timer accurate to within 1/30 sec or 10%

c) if mechanical timer accurate to within 1/20 sec or 15%

18. Xeroradiography

only tungsten target tubes to be used

19.1) **DENTAL AND CHIROPODIC**

a) for any setting, coefficient of Variation <.08

b) if fixed mA, Timer accurate to within 1/30 sec or 10%

c) kVp accurate to within +-8%

20.1) except for Panoramic or Cephalometric machines, Dental

beam size at end of cone 7cm maximum

21. Panoramic machines

beam size within 2% FFD of slit size

22. Cephalometric machines

maximum beam size 31cm x 38cm at image receptor

## 7 MAINTENANCE AND CALIBRATION

Proper maintenance of equipment is required in order to provide the most effective and efficient patient care. The benefits of a well-functioning maintenance programme are: minimization of equipment down-time, consistently high image quality, and assured patient and user safety. Although these Guidelines deal mainly with radiation-related safety factors, the large number of mechanical and electrical components involved in x-ray equipment present many potential hazards to both the patient and the operator, some of which could cause serious injury.

Under the term maintenance, we can consider three areas:

Preventive maintenance, which is done on working equipment in order to keep the equipment operating at a high performance level,

Calibration,

Service, ie. the repair of faults affecting the operation or use of the equipment.

### 7.1 Handling Of Fault

A protocol must be set up in the department for the handling of different degrees of faults, from their detection through to the completion of the repair. There should be one person, either the technical administrator or the QA technologist who is responsible to follow through this entire process. Any problem, no matter how small should be reported to this person by the user of the equipment on a form provided for this purpose (a supply to be kept in the x-ray room) describing the problem as completely as possible, with all pertinent operating settings listed. This will greatly facilitate diagnosis of the problem. The QA technologist should then evaluate the seriousness of the problem,and make a preliminary diagnosis. Based on the severity of the problem, the appropriate service person should be contacted.

After the completion of the repair, the QA technologist should perform an abbreviated acceptance test. This involves retesting the function which was malfunctioning and verifying that other associated functions have not been inadvertantly altered. A comparison of tube output with the recorded baseline value which should be kept in the QA log for that room is essential. Only after these tests have been successfully completed should the repair be deemed complete. The service engineer should provide a description of work done and parts replaced, which should be kept in the room log book.

| TASK | PERSON RESPONSIBLE |
|---|---|
| 1. Detection + Reporting | RT. QA technologist |
| 2. Diagnosis + Schedule Repair | QA technologist |
| 3. Repair | Service Engineer or QA technologist |
| 4. Verification of repair | QA technologist |

## 7.2 Preventive Maintenance

Preventive maintenance is service performed before faults interfere with the diagnostic quality or safety of the equipment. Preventive maintenance should be performed:

-at frequencies based on past experience with equipment

or

-following a schedule as laid down by the manufacturer and based on the results of quality assurance checks.

General preventive maintenance involves the cleaning of the equipment, mechanical safety checks and lubrication. Some of these procedures can be performed as part of the quality assurance test programme by the QA technologist , depending on his or her capabilities. Items to be checked include:

1. Filters and fans on all cabinets (since temperature changes will affect the calibration and operation of delicate electronic components)
2. Suspension cables (for fraying and tension)
3. Electrical cables at flex points for breakage
4. Bucky operation and alignment with x-ray beam
5. Collimator operation and alignment
6. Lubrication of motors and table bearings
7. Light output of viewboxes
8. Cleaning of processors
9. Darkroom light leaks, water temperature stabilization
10. Locks and interlocks
11. Loose bolts and damaged protective devices
12. Presence of correct x-ray beam filters
13. Mechanical condition of grid
14. Screens, mechanical condition, screen-film contact, light leaks, speed (optical density/milliroentgen)

## 7.3 Calibration

By calibration is meant the determination of a relationship between the control settings or meter readings of the equipment and the actual values of those factors being controlled. For example the x-ray generator may at a setting of 80 kVp yield an actual kVp output of 75 kVp. Calibration of the generator reveals that the actual value is 5 kVp lower than the setting.

In the ideal case, equipment would be adjusted such that the values of control settings and meter readings are identical to the actual values of equipment performance. This is desirable since it makes for simplicity and convenience in equipment use and minimizes the likelihood of error in selecting machine settings. In some cases it is not possible or practical to adjust equipment in this manner. In such cases, provided that the equipment operates consistently, it is acceptable to present the calibration as a clearly-worded table posted prominently on the equipment describing the proper control settings to obtain the desired equipment operation. In the above example the table would indicate that to obtain 75 kVp, the kVp selector should be set at "80" and to obtain 80 kVp the selector should be set say at "84". In some cases this may be much more practical or cost effective than attempting to adjust equipment such that control settings agree perfectly with output values.

Calibration is done so that the emission of radiation from the equipment and the image quality can be consistent from image to image. As well, when equipment is calibrated the controls can be changed in operation to obtain predictable changes in equipment performance. It is only when equipment is calibrated that technique charts will be useful.

Calibration should be done by those who are properly trained to make measurements on x-ray equipment. This may be the quality control technologist, a medical physicist or a service representative of the equipment manufacturer. Adjustment, if required, should be done by properly-trained personnel familiar with the equipment. When calibration is done regularly, adjustment and servicing to obtain proper results can be done promptly after a drift in equipment performance has occurred.

### 7.3.1 "Normal range of use of equipment"

Most x-ray equipment is designed such that it will operate over a very large range of kilovoltage, tube current and exposure time. In certain applications equipment is restricted in its mode of operation to a limited range of these settings. Under such conditions the HARP regulations specify that the equipment need only meet standards over its "normal range of use". This allows the effort of calibration to be directed toward the areas which will have the greatest effect on patient dose and image quality and can considerably reduce the cost of calibrating equipment. At the same time equipment which is only calibrated over part of its possible range of control settings must be clearly marked to that effect and no attempt must be made to use it under conditions in which its performance is not predictable.

## 7.4 Service

The provision of service can be established by three different methods depending on the size and preference of the facility. Each of these methods have benefits and drawbacks which must be evaluated before implementation.

1. In-house service.
    a. all repairs done by in-house service person/group
       stock of repair parts required
       liaison with manufacturers required
       training is required on specialized equipment
    b. preventive maintenance servicing (PMS) and minor repairs done in-house with major repairs by others

2. Vendor service
    a. comprehensive service contract
        a. PMS twice a year
        b. emergency response, minimum downtime
        c. parts included
    b. request service
        a. cost = travel time + labour time + parts

3. Third party service
    a. can be cheaper
    b. can provide same degree of service

Any servicing agreement must specify the work that will be performed under the contract, and that an acceptance test of the equipment will be required before the repair is deemed complete.

Calibration should be performed only if there is a variation from the established baseline for the room or department. Service should be performed by individuals with training appropriate to the maintenance of high voltage electrical systems and with experience on x-ray equipment. Some maintenance can be done in-house by an individual with a good mechanical and electrical aptitude, as long as the appropriate service manuals are on site.

# 8 MEDICAL RADIOLOGY GUIDELINES

In terms of the number of x-ray machines in the province and the number of individual exposures per annum, medical radiology is not the leading radiological specialty in Ontario - that place is held by dental radiology. However, the average medical radiological examination irradiates a much larger volume of tissue and has a higher potential for harm to the patient than the average examination in the other specialties covered by the HARP Act. Furthermore, the range and complexity of investigations carried out in medical radiology departments and clinics are usually greater than in the other specialties. In total, therefore, medical radiology is by far the largest contributor to the population exposure of the people of Ontario and has the largest potential for a reduction in the overall detriment. The guidelines in this chapter are therefore of particular importance.

This chapter is addressed both to physicians who prescribe medical radiological examinations, including general practitioners, and those who carry out and interpret such examinations, whether radiologists or not. The chapter begins with a discussion of the general concepts for the use of diagnostic radiation. The problem of the protection of the patient in medical x-ray examinations both in the prescription and in the performance of the examination is then addressed. Recommendations are provided for the minimization of the risks of fetal irradiation and for appropriate action to be taken when inadvertent irradiation has occurred. Protection of personnel who must work in the vicinity of x-ray equipment is discussed. Finally, the elements of a quality assurance programme are reviewed.

## Patient Protection In Medical Radiology

The term 'Patient protection' is used here to cover: (a) the selection of patients for medical radiological examinations, so as to ensure that each such examination is both necessary for the well-being of the individual concerned and appropriate to the clinical problem; and (b) the performance of a medical radiological examination in such a way as to minimize the radiation exposure of the patient, consistent with the requirements of diagnostic image quality. We begin with a general discussion of the problem (section 8.2.1), leading to guidelines of a general nature relating to patient protection, followed by specific guidelines on the selection of patients (8.2.2) and the performance of medical radiological examinations (8.2.3). Section 8.2.4 provides some guidelines on the management of female patients following deliberate or inadvertent irradiation of the foetus.

## 8.1 General guidelines

The guidelines in this and the following two sections relate to the indications and clinical needs for medical radiological examinations and the performance of these examinations in as safe a manner as possible. Almost by definition such guidelines must be inadequate since a satisfactory document of this kind would have to precis the total practice of medicine. The recommendations are therefore limited to some broad generalizations, which are based mainly on two publications:

1. A Rational Approach to Radiodiagnostic Investigations. World Health Organization, 1983*
2. X-ray Equipment in Medical Diagnosis, Part A: Recommended Safety Procedures for Installation and Use (Safety Code 20A). Health and Welfare Canada 1981 **

For further information, the reader is urged to study the original publications, both of which are well written, easy to read, and include extensive bibliographies.

The problem addressed in this section is the elimination or reduction of unproductive radiology by appropriate selection of patients and choice of technique. It must be said, however, that radiology is so widely used as a diagnostic tool that any attempt to limit its scope faces immense difficulties. There is public pressure for x-ray examinations and, furthermore, patients expect a perfect result. The fact that a simple x-ray causes little discomfort or inconvenience tends to reinforce this expectation. For their part, while physicians are usually aware that radiology may yield incomplete or erroneous results, they may not realize the extent of this problem. Legal regulations, such as those pursuant to the HARP Act, may attempt to reduce the incidence of error by defining standards for

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Footnote

* The World Health Organization report has been reviewed by the Canadian Federal-Provincial Diagnostic Imaging Advisory Group (DIAG), the Subcommittee on Special Services in Hospitals and the Advisory Committee of Institutional and Medical Services, all of which recommended that it be distributed to practicing physicians, hospitals and medical education programs. More specifically, DIAG:

A. Accepts that this Report's recommendations, if adopted, could substantially decrease the number of clinically unproductive radiological examinations in Canada.

B. Endorses the incorporation of these recommendations into undergraduate medical education.

C. Recommends that provincial and preventional health authorities and organizations undertake to remove the factors limiting their adoption.

D. Sees these recommendations as illustrative examples of limiting wastage of scarce resources by applying diagnostic algorithms.

** This Safety Code is currently (June, 1987) under revision, but it is not expected that major changes will be made in the recommendations relating to procedures as distinct from equipment.

equipment and related matters, but it would be wholly inappropriate for such regulations to interfere with the clinical process per se, including the referral of patients and the choice of modality and technique. It should be the responsibility of the various professional bodies to monitor and evaluate radiological practice by the peer review process.

Two important aspects of medical radiology are cost and radiation exposure. Radiology accounts for a significant part of the overall cost of health care, 6 - 10% in industrialized countries. At the same time, medical radiology is the largest source of man-made exposure of the population. A principal objective of the HARP Commission is to reduce population exposure in Ontario by ensuring that equipment and personnel operate within defined safety standards. At the same time, the Commission desires to rationalize radiological coverage and utilization within the province, including the reduction of unnecessary radiology, but recognizes that this objective lies outside the scope of legal regulations. The preferred procedure is to identify the more common radiological examinations and to disseminate guidelines relating to these examinations as widely as possible. Such guidelines must include the selection of patients for the examination in question. Unfortunately, it is never possible to make a perfect selection of patients for any diagnostic examination and no recommendations can completely eliminate the unproductive use of x-rays. The guidelines which follow must be viewed in this realistic context.

### 8.1.1 Inherent Limitations

Practitioners must be made aware of the inherent limitations of each test, and these limitations must be related to the local prevalence of the suspected disease process. More specifically, when searching for evidence of a disease that has a low prevalence in any population, the physician must recognize that the yield of a diagnostic procedure will also be low. Therefore, because disease patterns are constantly changing, there must be regular review and re-examination of radiological procedures so that medical practice can respond to these changes.

### 8.1.2 The ALARA Principle

In the context of the HARP programme the application of the ALARA Principle (As Low As Reasonably Achievable) to diagnostic radiology involves three stages:

1. **No x-ray practice shall be adopted unless its introduction produces a positive net benefit; that is, the examination must be JUSTIFIED.**

2. **All x-ray exposures shall be kept As Low As Reasonably Achievable (ALARA), economic and social factors being taken into account; that is, the procedure must be OPTIMIZED to reduce the hazard to the patient.**

3. **The ENTRANCE EXPOSURE LIMITS, as set out in Table 6 of the Regulations must not be exceeded for test exposures of the standard procedures listed in that table.**

Following the second stage in this process should result in patient exposures considerably lower than these limits. In essence, it is the duty of all health care professionals involved in the practice of radiodiagnosis to ensure that the patient receives the maximum benefit from radiology, with the least risk. Furthermore, because resources are finite, cost-effectiveness must be considered. For a more detailed discussion of the ALARA Principle in medical radiology, see Section 1.4 of these Guidelines.

### 8.1.3 Consultation

The quality of an x-ray examination is frequently related to the degree of consultation between the radiologist and the referring clinician. For the more complex examinations, direct consultation, leading to the selection of the most appropriate image modality, is essential. For common examinations, i.e. the majority, it remains the responsibility of the referring clinician to state the nature of the clinical problem in sufficient detail to enable the selection in the radiology department of the most appropriate modality and technique. Without this information the wrong views, or inappropriate exposures, may be utilized. Medical practitioners should have more frequent recourse to radiological consultation and they should be made aware of the necessity, on occasion, of not requesting an examination.

### 8.1.4 Sensitivity and Specificity of Examination

The sensitivity of an examination is defined as the percentage of all patients with the disease for whom the examination yields a positive result. The specificity of an examination is the percentage of all patients without the disease for whom the result is negative. Productive and efficient use of x-rays requires the maximization of both sensitivity (i.e. few false negative results) and specificity (i.e. few false positive results). Proper understanding of these principles must lead to better utilization of x-ray examinations and hence to a decrease in the unproductive use of radiation. This awareness should lead to such questions as "Is this x-ray examination indicated for this particular patient?" and "If the result is positive (or, equally important, negative), how will that affect the management of the patient?

It must always be remembered that no radiological examination is perfect. To the inherent limitations must be added observer error, which encompasses faults in perception and faults in interpretation. Training and experience, coupled with good radiographic and radiological techniques, reduce the error rate but cannot eradicate it entirely.

### 8.1.5 Development of Policies and Procedures

All x-ray facilities, large and small, should develop a body of policies and procedures for the operation of the facility, with particular emphasis on:

- routine views
- communication of clinical requests
- communication of final interpretation
- quality assurance program

In a hospital environment, an x-ray facility is obliged by the accreditation process to develop and document its policies, but this process should be carried out whether the facility undergoes accreditation or not.

### 8.1.6 Previous Examinations

No request for a radiological examination should be made without determining whether a similar examination has been performed recently, rendering a new examination unnecessary. It must be emphasized that previous radiographs are part of the patient's record and are essential when interpreting a new examination.

### 8.1.7 Continuing Medical Education

Like all other health professionals, those involved with diagnostic imaging should undertake regular upgrading courses and continuing medical education should be identified as a high priority item. This applies not only to physicians, including radiologists, but also to the technical and nursing staff who may be involved in these procedures. Of particular importance are those physicians who are not trained as radiologists yet utilize x-ray facilities in their clinical practice. Current examples are cardiologists during cardiac catheterization, orthopedic surgeons during surgical procedures and gastroenterologists. At present none of these specialists have much training in imaging technology and this situation might lead to excessive and unnecessary use of ionizing radiation.

### 8.1.8 Medico-Legal Demands

Neither rules and regulations nor guidelines can diminish the enormous pressures exerted on the practicing physician by the litigation process. These pressures undoubtedly result in some x-ray exposures which are not strictly indicated by the medical condition of the patient. This is an unnecessary evil with which we must live, at least for the present. It is impossible to provide general guidelines for dealing with this situation since both the nature of the problem and the possible remedies vary from place to place and even from time to time. Thus a local solution is needed and it is recommended that appropriate professional and political discussion be held in order to formulate guidelines for dealing with this problem in each facility.

### 8.1.9 Peer Review Process

Professional bodies should continue to develop realistic, cost effective peer review processes, with emphasis on referral patterns, clinical indications for x-ray examinations and the diagnostic quality of the images produced in the facility.

### 8.1.10 Summary of General Guidelines

Although the general guidelines just presented may seem obvious, an in-depth analysis as to whether or not they are all followed could benefit most x-ray facilities. If these principles were emphasized during the formative years in undergraduate and residency programs, there would be a general improvement in the utilization of x-ray facilities as these physicians develop their practices in a somewhat more enlightened environment. In addition, the principles should be emphasized to other medical practitioners and x-ray technologists as they evolve in their chosen areas of expertise.

## 8.2 Guidelines for the prescription of medical x-ray examinations (except mammography and chest screening: see 8.2.1 and 8.2.2.)

The guidelines in this section are addressed to the medical practitioner who prescribes an x-ray examination but does not himself/herself carry it out. The practitioner is in a unique position to reduce unnecessary x-ray exposures, both to the individual patient and to the population of Ontario, by ensuring that all requested examinations are clinically justified. Specific guidelines are as follows:

a) The prescription of an x-ray examination should always be based on a clinical evaluation of the patient.

b) The purpose of an x-ray examination should always be to obtain information relevant to the diagnosis and/or treatment of the patient.

c) Examinations should not be prescribed where there is no prior clinical evaluation of the patient, as in pre-employment and screening examinations. (See, however, Sections 8.2.1 and 8.2.2.)

d) Except in emergency situations, the physician should determine whether there has been any previous x-ray examination which would make a further examination unnecessary, or allow an abbreviated examination to be ordered. The practitioner should examine relevant previous radiographs or reports along with the clinical evaluation of the patient.

e) When prescribing a radiological examination, the physician should specify precisely the clinical indications and information required.

f) Only essential investigations of the abdomen and pelvic area should be prescribed for a pregnant or suspected pregnant woman. Elective radiography of the abdomen or pelvic area must be avoided, where "elective" means an examination that does not contribute to the diagnosis or treatment of an immediate illness.

g) Radiography should not be used for the determination of abnormal presentations of the foetus, for placental localization or, in general, for routine pre-natal examinations. Other techniques, such as ultrasonography, are better suited for this purpose.

h) Pregnant women, or women who may be pregnant, should not be accepted for mass screening x-ray examinations.

i) Fluoroscopy usually results in a significantly higher radiation exposure of the patient than radiography. A fluoroscopic procedure should therefore be prescribed only when equivalent information cannot be obtained from radiography, as in dynamic investigations and the guiding of catheters. Fluoroscopy should never be prescribed simply as a substitute for radiography.

j) When a patient is transferred from one physician or clinic to another, any radiographs or reports should accompany the patient and should be reviewed by the consulting physician.

### 8.2.1 Guidelines for radiographic examination of the breast (Mammography)

In view of the fact that repeated mammographic examinations can accumulate a significant radiation dose, the following general guidelines should be observed. They are based on the 1980 statement of the American Cancer Society (ACS, 1980), as modified in 1983 (see Holleb, 1985), on the revised recommendations of the American College of Radiology. (ACR, 1982), and on the recommendations of the Ad Hoc Committee on Mammography of the Canadian Association of Radiologists (CAR).

The recommendations of these organizations are summarized in Table 8-1 and are based mainly on the results of the Health Insurance Plan of New York (HIP) Study, a randomized trial, and on the Breast Cancer Detection Demonstration Project (BCDDP) which was not randomized. The HIP study showed a decrease in mortality from breast cancer in women over 50 who were screened with both mammography and physical examination (although the study design did not allow quantification of the individual contribution of the two tests). A Canadian randomized trial (Miller, 1983) is underway to answer this question and to test whether improvements in mammographic technology since the HIP study allow mortality reduction in women 40-49.

A randomized study in Sweden suggests that there will indeed be a benefit in women in this age group.

The guidelines below are not intended to restrict the clinical freedom of individual physicians dealing with individual patients especially those with symptoms. Rather, they are meant to stimulate careful consideration before screening large numbers of women in the younger age groups and the potential risks that this is thought to entail. It should be noted that a properly conducted mammographic examination with modern equipment and image receptor (film/screen mammography) gives rise to an average breast dose of about 100 mrad total for two views (cranio-caudal and lateral). This corresponds to an entrance exposure of about 300 mR per view. The maximum entrance exposure permitted under the Regulations is 900 mR per view for film/screen and a 4 cm compressed breast. This exposure yields a dose of about 300 mrad for two views when the half-value layer of the beam is 0.31 mm Al (Hammerstein et al. 1979).

Recent studies (Feig, 1983a, 1983b, 1984; Feig and McLelland, 1983) suggest that, at 100 mrad dose per examination, the benefit of mammographic screening to women over the age of 40 exceeds the risk of radiogenic breast cancer by a considerable margin. For example, Feig (1983a) calculated that, for the age group 40-44, the initial mammographic screening results in a life-expectancy gain of 15.3 years per 1000 screenees, against a loss of 0.06 years due to the induction of cancer when the mean breast dose is 100 mrad.

With these introductory remarks, the following guidelines are suggested:

(a) Mammography should not be offered as a screening test to women of all ages.

(b) Annual mammography and physical examination by a trained examiner in women over age 50.

(c) Periodic screening of women of 40 years and over, using low-dose techniques, may be considered. Verification of the efficacy of screening women under 49 years awaits the results of the Swedish and Canadian randomized trials.

## Table 8-1 Recommendations For Mammography On Asymptomatic Women

| Age: 35-39 | | 40-49 | 50 + |
|---|---|---|---|
| CAR* | baseline mammogram | upon advice of physician | annual mammography |
| ACR** | " | baseline with repeats<br>1-1 1/2 years | " |
| ACS*** | " | annual or biennial mammography | " |

* Ad Hoc Committee on Mammography, Canadian Association of Radiologists

** American College of Radiology

*** American Cancer Society

### 8.2.2 Radiological chest screening

(a) The use of mass radiological screening should be considered only in areas of high incidence of tuberculosis or in special population groups who may be particularly susceptible to lung disease. The selection of population groups for x-ray screening should be based upon the probability of discovering a significant number of cases of cardiopulmonary disease and on the availability of treatment facilities for these individuals. This policy excludes the use of mass x-ray screening for tuberculosis and other chest diseases.

(b) Routine hospital admission chest x-ray should be taken only in identified high risk groups.

(c) Chest x-rays should not be normally required as a routine part of pre-employment medical checks or for admission to educational institutions.

## 8.3 Performance of diagnostic x-ray examinations

The guidelines below are addressed to physicians who carry out x-ray examinations at any stage from the prescription of the number or type of views, to the actual performance of the procedure or the interpretation of the radiographs. The general recommendations below are followed by more specific recommendations for fluoroscopy and radiography in pregnancy.

(a) Untrained medical practitioners should not operate x-ray equipment, or be responsible for the use of such equipment.

(b) Specialized studies should be undertaken only by, or in close collaboration with, a qualified radiologist.

(c) The number of radiographic views required in an examination should be kept to the minimum practicable, consistent with the clinical objectives of the examination.

(d) Fluoroscopy should not be used when an equivalent result can be obtained from radiography (see 8.4 below).

(e) If a radiograph contains the required information, repeat exposures should not be prescribed simply because the radiograph is not of the "best" diagnostic quality.

(f) Details of x-ray examinations carried out on a patient should always be entered in the patient's clinical record.

## 8.4 Performance of fluoroscopic examinations

The regulations pursuant to the HARP Act mandate the use of an image intensifier for fluoroscopy. Fluoroscopy without image intensification is illegal in Ontario. While the use of a video camera/TV monitor system for viewing the output phosphor of the intensifier is not compulsory, a system of this kind is strongly recommended.

The following recommendations, additional to those given above for general radiography, are made with respect to fluoroscopy:

a) Fluoroscopy should be carried out only by, or under the immediate supervision of, a radiologist or physician properly trained in fluoroscopic procedures. It is hazardous both to the patient and the staff for an untrained physician to carry out fluoroscopy.

b) All fluoroscopic procedures should be carried out as rapidly as is consistent with the diagnostic requirements and using the smallest practical x-ray field size.

c) The exposure rate at the patient entrance surface should be the lowest value consistent with the required diagnostic examination. (Section 16 of the Regulations prescribe maximum and average exposure rates for image intensifiers with zinc cadmium sulphide and cesium iodide input phosphors.)

d) When automatic brightness control of the image intensifier is used, the operator should monitor the x-ray tube current since this can rise to high values without the knowledge of the operator. If possible, the kilovoltage should also be monitored.

e) Mobile fluoroscopic equipment should be used for examinations only when it is impractical to transfer a patient to a permanent fluoroscopic installation.

f) Cinefluorography produces the highest patient doses in diagnostic radiology because the tube current is normally higher and the potentials used (70-80 kVp) are generally lower than in ordinary fluoroscopy. This technique should be used only where significant medical benefit is expected, relative to the use of other techniques.

## 8.5 Radiography of the pregnant woman: Precautions

Radiography of the pelvic area of a pregnant woman irradiates both the patient's ovaries and the whole body of the embryo or foetus. Irradiation of the unborn embryo/foetus increases the infant's risk of somatic effects (congenital abnormalities and childhood malignancy) and also increases the risk of genetic effects in subsequent offspring. Every effort should therefore be made to avoid unnecessary irradiation of a woman known to be pregnant or who might be pregnant. This is particularly important during the first four months when the potential for radiation damage is greatest. Clearly, however, if a radiological examination is required for the diagnosis or management of an urgent medical problem, and there is no alternative way of obtaining the same information, then it must be done, irrespective of whether the patient may or may not be pregnant. The following recommendations apply to pregnant or potentially pregnant women:

a) When essential radiography of the pelvic area or abdomen is carried out, the exposure should be kept to the absolute minimum and full use should be made of gonadal and other shielding to the extent that such shielding does not compromise the objectives of the examination.

b) If a radiographic examination of the foetus is essential and non-x-ray alternative modalities are inadequate, the prone position should be used where this is practical. This has the effect of shielding the foetus from the softer components of the x-ray beam and hence reducing the foetal dose.

c) Essential radiography of the chest, extremities, etc. of a pregnant woman should be carried out with a well-collimated beam and with additional shielding of the abdomen and pelvis.

### 8.5.1 Management of a pregnant woman after exposure to x-rays

In spite of the precautions outlined above, it sometimes happens that a pregnant woman is purposely or inadvertently irradiated in the abdomen or pelvic area.* This can happen, for example, if the woman is involved in an accident or other emergency, or if she is found to be pregnant subsequent to an x-ray examination. In such cases both the patient herself and her physician will wish to know the chances of radiation injury to the unborn child. The probability of injury depends on the stage of gestation and the radiation dose received by the embryo or foetus. The first step therefore, is to obtain an estimate of the foetal dose. This is a complicated calculation which should be undertaken only by a qualified medical physicist. The physician is therefore advised to consult with a medical physicist and provide the following information:**

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* X-ray examinations not involving the abdomen or pelvis will generally result in an insignificant dose to the embryo or foetus and are not normally cause for concern.

** In case of difficulty in locating a local medical physicist, the HARP Commission telephone (416) 963-1030 will provide a contact name and telephone number.

a) Type and number of radiographic exposures plus the relevant entrance exposure information as determined in the QA programme.

b) Type of fluoroscopic examination, if any, including total fluoroscopic exposure time (estimated if necessary), field size and maximum entrance exposure rate as determined in the QA programme.

c) Details of x-ray equipment used, including waveform (single or three-phase) and added filtration.

d) For each projection: type of projection, kVp, mA, exposure time (or for photo-timed exposures, average mAs for this projection), half-value layer, geometry (source-surface distance, source-image distance). It is not usually necessary to have details of the film-screen combination and grid, but this information can be helpful when the main exposure factors are unavailable.

e) For fluoroscopy: details of the image intensifier, i.e. ZnCdS or CsI, whether or not there was automatic brightness control, field size. Quality assurance data relating to average patient exposure rate, if available, are useful.

f) For computed tomography (CT) examinations: full technical details, including the make and model of the scanner, and the complete scan protocol especially kVp, mA, exposure time per slice, slice thickness and number of slices.

g) Data relating to the patient, i.e. age, height, weight, lateral and AP dimensions in the region irradiated.

h) Details are also needed of any other radiological examinations carried out at the same time as the x-ray examination. For example, the patient may have received a radionuclide scan in a department of nuclear medicine.

Given the above information, in as complete a form as possible, both for exposures directly irradiating the foetus and those not involving the foetus in the direct beam, the medical physicist will be able to estimate the foetal dose. If, as is usually the case, some of the data are unavailable, the physicist has to estimate the values of the missing factors and this increases the uncertainty attached to the final result. The largest uncertainty usually relates to the total exposure time in fluoroscopy and it is therefore important that this time should be routinely recorded in the patient's notes, especially where direct exposure of the abdomen or pelvis of a female patient is involved. The final estimate of the foetal dose may be subject to an uncertainty of ± 50%, but in most cases this does not affect the decisions concerning the subsequent management of the patient.

The following guidelines are offered to the physician caring for a pregnant woman whose unborn child has been irradiated, but it is strongly suggested that further consultation is desirable with a physician or scientist who has made a special study of the effects of ionizing radiation in the embryo and foetus.

The effects of x rays during pregnancy depend on the radiation dose received by the embryo/foetus, the dose-rate and fractionation, and the stage of gestation when the exposure occurs.

Possible radiation injuries are pre-natal death (which is asymptomatic in the early days of pregnancy), growth retardation, malformations (especially of the central nervous system), induction of childhood cancer and genetic defects in subsequent generations. The first three effects are believed to be "non-stochastic" (see section 2.1.3 of these Guidelines) and to require a minimum or threshold dose.

## Non-stochastic effects

The value of this threshold dose is considered to be between 10 and 100 rads, depending on the particular effect and the stage of gestation (Brent and Gorson (1972); UNSCEAR (1977); Pizzarello and Witcofski (1982)). The "Guide to Good Practice" of the American College of Radiology (ACR, 1985) assumes a minimum dose of 10 rads for prenatal death, malformation, growth retardation and mental retardation. **It should also be noted that the incidence of congenital defects of unknown origin, regardless of radiation history, is 4-6 percent. NCRP Report 54(1977) comments that: "For any individual case, the increased risk of such effects for doses below the 10-rad level, received at any stage of pregnancy is very small compared with this normal risk."**

## Childhood cancer

The induction of cancer during the first 10 years of life, especially but not exclusively leukemia, is believed to be non-threshold, i.e. to have a finite probability for any dose although there is no proof of this and the matter remains controversial. Accordingly, a conservative approach is usually adopted and the observed induction rates at doses of 10-100 rads or more are extrapolated linearly down to the dose levels (~1 rad or less) normally associated with diagnostic exposures. On this basis, a dose of 1 rad to the embryo/foetus, at any stage of gestation, may increase the probability of cancer during the first 10 years of life from about 0.05% (natural prevalence) to about 0.1% (Mole, 1979). Another estimate, for the first 15 years of life, suggests that 1 rad may increase the incidence from about 0.07% to about 0.17% (Swartz and Reichling, 1978). Thus, in terms of the *increase* in incidence, relative to the natural incidence, the induction of childhood cancer is the largest single risk of x-ray exposure during pregnancy. However, the *absolute* risk for typical foetal doses (<1 rad) is very small, in fact less than for some non-irradiated groups such as siblings of leukemic children (about 0.14%) and children with Down's syndrome (about 1.05%) (Brent and Gorson, 1972).

## Genetic effects

Very little is known about the induction of genetic effects when the embryo/foetus is irradiated at dose levels associated with diagnostic radiology. Mutagenesis as a result of irradiation of human foetuses has never been directly demonstrated, but we assume from animal experiments at high dose levels that the effect does occur. The dose required to double the spontaneous mutation rate in humans is believed to be about 50 rads, and a linear extrapolation to

1 rad leads to the conclusion that any increase in the mutation rate due to diagnostic exposures must be very small. Swartz and Reichling (1978) comment that, "We can confidently tell any individual woman that the radiation she has received has negligible chance of causing a genetic effect on her child or its children." These authors add, however: "Because genetic changes may enter the gene pool of the population, it is desirable to minimize such changes by minimizing radiation exposures to the gonads." This recommendation can, of course, be generalized to apply to any diagnostic exposure of the abdomen and pelvis of a pregnant, or potentially pregnant, woman.

## 8.6 Protection of the patient: Final word

We have endeavoured to provide both general guidelines and specific recommendations for the prescription and performance of medical x-ray examinations. It has not, however, been possible to cover every situation and every type of examination described in textbooks of diagnostic radiology, still less to encompass all available imaging modalities. It is nevertheless hoped that the text of this chapter is sufficient to raise the level of concern of all involved in the referral and performance of radiographic examinations and related imaging studies. As the tools for diagnostic imaging expand and improve, the decision as to which examination, if any, to request for a given patient becomes more complex and there is a corresponding increase in the complexity and range of variables in the carrying out of a given examination. Emphasis must therefore be placed on the development of algorithms for the diagnosis and management of common clinical presentations. Tomorrow's medical radiology will demand more communication, and more education.

## 8.7 Protection Of Personnel In Medical Radiology

These guidelines are not intended to provide full coverage of the protection of personnel in the medical and dental applications of x-rays. Only selected situations of major importance, relating to (a) the use of mobile x-ray equipment and (b) special radiological procedures, will be dealt with here. The reader is, however, referred back to section 3.9.2 for a discussion of the protection of personnel during fluoroscopic examinations.

a) Mobile units should normally be used only if the condition of the patient makes it inadvisable for the examination to be carried out with a stationary unit in the main x-ray department. (However, it does sometimes happen that a mobile unit is the unit of choice for a particular examination, for reasons other than convenience of location.)

b) During operation of a mobile unit, the primary beam should be directed into an unoccupied area if at all possible, and every effort must be made to ensure that the beam does not irradiate any other person in the vicinity of the patient.

c) When exposures are made with a mobile unit, the operator should (i) stand at least 3 metres from the x-ray tube, (ii) stand out of the direct beam, and (iii) wear a protective apron or utilize some other form of radiation protection.

d) In a capacitor discharge x-ray unit, a residual charge is left in the capacitors after an exposure has been made. This can result in the emission of x-rays even though the exposure switch is not activated. The residual charge should therefore be fully discharged before the unit is left unattended.

e) In many special radiological procedures the radiologist and other participating personnel can be subjected to appreciable scattered radiation from the patient when the x-ray beam is on. Procedures in this category include cardiac catheterization cystoscopic radiography, hystero-salpingography, needle biopsies of the lung, transhepatic needle cholangiography, pancreatography and other similar procedures. Therefore:

(i) All personnel should wear protective glasses and clothing.

(ii) All personnel should remain as far from the patient as practical, unless adequate scatter shields can be incorporated into the x-ray equipment.

(iii) Protective devices provided with the x-ray equipment (e.g. shielded panels, leaded drapes, extended collimator cones) should be used whenever they do not interfere unduly with the diagnostic procedure.

(iv) The smallest x-ray field should be used that is consistent with the procedure.

f) Angiography is potentially one of the sources of greatest exposure to personnel, since it requires the presence of many people close to the patient and also involves both multiple radiographic exposures and extended periods of fluoroscopy. All personnel should be aware of the radiation hazards involved in angiography.

Furthermore:

(i) Full use should be made of the protective devices provided with x-ray equipment (e.g. shielded panels, leaded drapes, bucky slot covers).

(ii) All personnel should wear protective glasses and clothing.

(iii) All personnel should carry one or more personnel dosimeters (TLD badges) worn beneath the lead apron to monitor the radiation actually reaching the body. An additional dosimeter worn on or near the collar can be used to monitor the radiation reaching the head and neck of the individual.

(iv) Those who are not required to be immediately adjacent to the patient during the procedure should stand as far back as possible and preferably behind a protective shield.

(v) Where feasible, special shields should be constructed and used, in addition to those provided with the x-ray equipment.

## 8.8 Quality Assurance In Medical Radiology

Table 8-3 outlines the components of a minimum quality assurance programme for a medical x-ray facility. The table is copied from Table 5 of the Regulation pursuant to the HARP Act, but also includes references to the appropriate sections of Chapter 5 of these Guidelines in which the various tests are described and discussed.

Since this programme is a minimum one, there is no difference between the requirements for a small radiology office and a large hospital department, except of course, where the facility lacks a particular type of equipment such as a phototimer or a tomograph.

Where there are alternative methods of carrying out the same test, the small facility will no doubt choose the method that is easiest to perform and/or requires the least equipment, although this will not necessarily yield as much information as a more complex test. Nevertheless all tests described in Chapter 5 satisfy the requirements of the Regulations. All facilities, large and small, are urged to develop QA programmes appropriate to their needs and resources beyond the minimum programme required by law, in the interest of the safe and efficient use of radiation. Books and other sources of further information on QA procedures are included in the Reference list at the end of these Guidelines.

## Table 8-3 Quality Assurance Procedures In Medical X-ray Facilities

| Test or Procedure | Frequency | Section in Guidelines |
|---|---|---|
| Photographic quality control | Every operational day | 5.1 |
| Patient entrance exposure measurements | Every six months and upon alteration or servicing of the machine | 5.2 |
| Collimation | " | 5.3 |
| Half-value layer | " | 5.4 |
| Phototiming parameters including operation of back-up timer | Every six months | 5.8, 5.9 |
| Fluoroscopic parameters, including: | | |
| (a) maximum patient entrance exposure rate | Every six months and upon servicing of the machine | 5.10 |
| (b) resolution | Every six months and upon servicing of the machine | 5.11 |
| (c) limit timer | Every six months and upon servicing of the machine | 5.12 |
| (d) automatic brightness control | Every six months and upon servicing of the machine | 5.10 |
| Tomographic parameters, including fulcrum accuracy, thickness of cut and mechanical stability | Every six months | 5.13 |

# 9 DENTAL GUIDELINES

The use of dental equipment is regulated by the Healing Arts Radiation Act and the Regulations under the Act (1985). The Act requires that a Radiation Protection Officer (RPO) be appointed to be responsible for the safe use of radiation; in the case of a dental installation the RPO must be a dentist licensed to practise in Ontario. In a one-dentist office, that dentist is the R.P.O. In a group practice, one of the dentists should be appointed as the R.P.O.

The Regulations prescribe a mandatory quality assurance program for each dental radiographic facility. These Guidelines provide information to aid the Radiation Protection Officer in establishing and maintaining the quality assurance programme and in carrying out his other duties under the Act and its Regulations.

The Guidelines address the relationship between the radiation exposure of the patient and the quality of the image, with optimization of the risk/benefit ratio as the object. The Guidelines also indicate what remedial measures can be taken to correct unsatisfactory situations in order to comply with the requirements of the Code.

## 9.1 The Alara Principle

An approach to the safe use of ionizing radiation has been developed by the International Commission on Radiation Protection (ICRP) and is summarized here:

1. No x-ray practice shall be adopted unless its introduction produces a positive net benefit; that is, the examination must be JUSTIFIED.

2. All x-ray exposures shall be kept As Low As Reasonably Achievable (ALARA), economic and social factors being taken into account; that is, the procedure must be OPTIMIZED to reduce the hazard to the patient.

3. The dose equivalent to individuals shall not exceed the limits recommended by the Commission for the appropriate circumstances; that is, recognized EXPOSURE LIMITS must not be exceeded during the course of the examination.

This system will now be discussed, as it applies in dentistry.

### 9.1.1 Justify

Since exposure to x rays carries with it an attendant risk, **A RADIOGRAPH SHOULD ONLY BE TAKEN WHEN A DIAGNOSTIC NEED FOR IT HAS BEEN ESTABLISHED BY PRIOR CLINICAL EXAMINATION BY A DENTIST.** Routine full-mouth and panoramic examinations before clinical examination are radiologically and ethically unacceptable.

### 9.1.2 Optimize

The dentist should satisfy himself that radiographic equipment, practices and procedures are such that the diagnostic information which is required by the examination is obtained with the minimum x-ray risk to the patient: i.e., the procedure is OPTIMIZED.

It has been well established that the x-ray risk to the patient can be minimized by attention to the following factors:

1. Film and film processing
2. Operating kVp and filtration
3. Beam geometry and alignment
4. The use of shielding aprons and thyroid collars

Attention to the first three of these will also result in improved diagnostic quality of the resulting image.

## 9.2 Exposure Limits

Table 7 of the Regulations sets out maximum allowable entrance exposure for a posterior bite-wing examination, as a function of nominal kVp. These values are reproduced here in Table 9-1. These limits have been established from data measured by the Ontario Ministry of Health X-ray Inspection Service in dental facilities across Ontario. It is possible with proper choice of equipment and technique and an effective quality assurance programme to produce high quality images at significantly lower exposures than specified in the Regulations.

In order to eliminate unnecessary exposure of patients in the dental use of x-rays, the recommendations provided in the following sections should be adopted.

Table 9-1 Maximum Entrance Exposures and Minimum HVL for Posterior Bite-Wing Radiographs (per film)

| Peak kilovoltage | Maximum entrance exposure in mR | Minimum HVL* (mm of Al) |
|---|---|---|
| 50 | 550 | 1.2 |
| 60 | 475 | 1.3 |
| 70 | 360 | 1.5 |
| (71) | (360) | (2.1) |
| 80 | 280 | 2.3 |
| 90 | 220 | 2.5 |

*HVL may be adjusted by changing the amount of Al filtration. However, Safety Code 22 of the Federal Radiation Protection Bureau (RBP, 1981) requires a minimum of 1.5 mm total Al filtration for operation at or below 70 kVp and 2.5 total Al filtration above 70 kVp.

## 9.3 Selection of Equipment and Materials

### 9.3.1 Film

The fastest film consistent with adequate diagnostic quality should be used. Use of Type E film reduces patient exposures by a factor of two compared to Type D, however, the image quality is also reduced when Type E is used.

### 9.3.2 X-ray unit

In the purchase of fixed kilovoltage units, those operating below a nominal 60 kVp should be avoided since, even with adequate filtration to satisfy the Regulations, the patient will receive considerable exposure from x-rays which are incapable of contributing to the image (see Figure 3-1, page 37).

At installation, every effort should be made to attach the unit to a stable, not-overloaded power supply, in order to eliminate the possibility of variations in kVp and mA due to line fluctuations.

## 9.4 Acceptance Testing

When acquiring a dental x-ray unit, it is required that the RPO sends written results of acceptance tests to the Director of X-ray Safety, Ontario Ministry of Health* within 60 days of installation to confirm that the x-ray machine complies with the requirements of the Radiation Emitting Devices Act (Canada) and its Regulations for new equipment or with the Healing Arts Radiation Protection Act and its Regulations for newly-installed used equipment. A checklist for acceptance testing under the RED Act is included here while a checklist for the HARP requirements is given in Chapter 6.

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*7 Overlea Blvd., 6th Floor, Toronto, Ontario M4H 1A8

As part of acceptance testing the entrance skin exposure should be measured, recorded and compared with the data in Table 9-1. This will allow the dentist to be aware of the exposure he is delivering to his patients, and to know how this compares to a standard. Once imaging has been optimized such exposure data can be used as baseline values for the quality assurance programme, further details of which are given in Section 9.5.

# RADIATION EMITTING DEVICES ACT - COMPLIANCE CHECKLIST - DENTAL UNITS

Date:____________________

Institution:__________________________

Mailing address:

Contact person:

Equipment:

Manufacturer:

Model number:

Serial number:

R.E.D. Act requirements*

2. (1) Safety features:

(a) x-radiation warning symbol, triangle, permanently affixed to the x-ray machine control panel;

(b) a warning sign that prohibits unauthorized use;

(c) electrical meters or other indicators that show

(A) the preset operating kilovoltage of the equipment when used in a variable milliampere-second mode, and
(B) the preset operating kilovoltage and milliamperage of the equipment when the tube current is fixed;

(d) warning lights that indicate

(A) when the filament of the x-ray tube is carrying current or when the control panel is energized, and
(B) when x-rays are being produced;

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*This list is a summary only. For exact wording of requirements, please refer to the R.E.D. Act and Regulations.

(e) an exposure switch that requires continuous pressure by the operator and the cable shall be of such a length as to enable the operator to stand at least 3 metres from the x-ray source;

(f) a timer such that

- (i) termination of an exposure causes automatic resetting of the timer to its original setting or to zero,
- (ii) an exposure cannot be initiated with the timer set at zero or its OFF position,
- (iii) repeat exposures cannot be initiated with recycling timers without the release of the exposure switch to reset the timer, and
- (iv) the production of x-rays is automatically terminated after

(A) a preset time interval, or

(B) a preset milliampere-second;

(g) a localizing cone or other device or appliance that limits the distance between the target within the x-ray tube and the skin of a patient to not less than 18 centimetres (panoramic examinations not less than 15 centimetres);

(h) collimators that

- (i) provide at least the same degree of attenuation for unwanted radiation as required of the x-ray tube housing, and
- (ii) limit the size of the useful beam

(A) at the image receptor of equipment designed for panoramic examinations, to a size that does not exceed by more than two per cent of the source-to-image receptor distance, each dimension of the scanning slit,

(B) to the size of the image receptor or a diameter of 30 cm, whichever is smaller, at a distance of 1.5 metres from the focal spot, in equipment that is designed for cephalometric examinations, or

(C) to a maximum linear dimension of 7 centimetres, at the end of the localizing cone or appliance described in paragraph (g), for all other equipment;

(i) radiation absorbing filters that

(i) are securely installed in the path of the useful beam, and

(ii) provide a total attenuation of the useful beam at least equivalent to that afforded by

(A) 2.5 millimetres aluminum, for machines designed to operate with x-ray tube potentials above 70 kilovolts (peak), and

(B) 1.5 millimetres aluminum, for machines designed to operate with x-ray tube potentials at or below 70 kilovolts (peak):

(j) a mark on the x-ray tube housing indicating, the location of the focal spot on the target;

(k) a lock on the x-ray machine control panel of a kind that requires the insertion of a key before x-rays can be produced and where removal of the key causes termination of the production of x-rays.

(2) Where more than one x-ray tube is controlled by one control panel, be designed to include, in addition the following safety features:

(a) an interlock such that it is not possible to energize more than one x-ray tube at the same time;

(b) on each x-ray tube housing an indication that the tube is connected and ready to be energized; and

(c) at the x-ray machine control panel, an indication of which x-ray tubes are connected and ready to be energized.

3. (1) Every extra-oral dental x-ray unit shall

(a) have the x-ray tube securely fixed and correctly aligned within the tube housing;

(b) maintain the x-ray tube head in its exposure position without drift or tipping during operation;

(c) be shielded such that emission of ionizing radiation other than from the x-ray tube assembly, when the machine is operated at its maximum kilovoltage and current rating, is such that the average exposure rate of x-rays to an object having a 10 square cm cross section and centred at 5 centimetres from any accessible surface of the unit, does not exceed 2.5 milliroentgen per hour.

(2) Every extra-oral dental x-ray unit shall bear

(a) on the external surface of the x-ray machine control panel, a permanent mark or label that sets out

  (i) the name of the manufacturer,
  (ii) the model designation,
  (iii) the serial number,
  (iv) the date of manufacture, and
  (v) the country of manufacture;

(b) on the external surface of the x-ray tube housing a mark or label that sets out

  (i) the name of the manufacturer,
  (ii) the model designation,
  (iii) the serial number,
  (iv) the date of installation of the tube in the housing, and
  (v) the country of manufacture.

4. Extra-oral dental x-ray equipment shall function under normal conditions of use in such a way that

(a) the preset kilovoltage is not able to be set below 50 kilovolts (peak);

(b) for any selected combination of kilovoltage, current and time greater than 1/30 second, the coefficient of variation of any 10 consecutive radiation exposures taken at the same distance within a time period of 1 hour is not greater than 0.05;

(c) the kilovoltage setting of the x-ray tube can be maintained at its selected value to within 3 kilovolts when the line voltage supply, having an impedance equivalent to 1 ohm, varies by plus or minus 10 per cent of its nominal value;

(d) if the x-ray tube voltage can be preset to 50 kilovolts (peak), a warning device gives a clearly visible or audible indication when the line voltage falls more than 10 percent of its nominal value;

(e) the timer shall

  (i) at any setting of 1/30 second or longer or 0.50 milliampere-second or greater, be capable of producing 10 consecutive radiation exposures with a coefficient of variation not greater than 0.05;

and shall, except in the case of equipment designed for panoramic examinations,

(ii) if the x-ray machine is operating in the fixed milliamperage mode, be capable of being set to control exposures as short as 1/60 second (or one cycle) and, at each timer setting, be accurate to within 1/60 second (or one cycle) or 5 percent of the set value, whichever is the greater, and

(iii) if the x-ray machine is operating in the variable milliamperage mode or variable time mode or both, be capable of being set to control exposures as short as 0.25 milliampere-second and, at each timer setting, be accurate to within 0.25 milliampere-second or five percent of the set value, whichever is the greater; and

(f) the leakage radiation at a distance of 1 metre in any direction from the focal spot of the x-ray tube does not exceed 100 milliroentgen in 1 hour under any exposure conditions within the rated limits of the x-ray tube.

## 9.5 Quality Assurance Programme

The mandatory quality assurance programme for dental facilities is specified in Table 3 of the Regulations and is summarized in Table 9-2 below.

The Act requires not only that the tests be performed, but also that thorough records be maintained of the results of the tests and actions taken to correct any deficiency revealed by the tests.

The quality control program should ideally be performed completely in-house. It is, however, essential that the daily photographic quality control is performed in-house. It is possible to have the last three tests performed by outside agencies, for example, the equipment-service technician. Alternatively, the dentist may receive by mail a sealed packet containing either a calibrated film or an array of thermoluminescent dosimeters (TLD's) and an aluminum absorber for determination of half-value layer. The packet is then placed in the same location that the x-ray beam would enter the patient and exposed using the same factors as for a bite-wing examination, and the packet returned to the agency. From this single test, the exposure, filtration and beam size and quality may be determined and reported to the dentist for his records. The report should also indicate deficiencies requiring attention.

### Table 9-2 Quality Assurance Procedures In Dental X-ray Facilities

| Test or Procedure | Frequency | Section in Guidelines |
|---|---|---|
| Photographic quality control | Every operational day | 9.5.1 |
| Patient entrance exposure measurements | Every twelve months and upon alteration or servicing of the machine | 9.5.2 |
| Collimation | Every twelve months and upon alteration or servicing of the machine | 9.5.4 |
| Half-value layer | Every twelve months and upon alteration or servicing of the machine | 9.5.3 |

### 9.5.1 Photographic quality control

The most direct way to evaluate photographic processing is to perform sensitometry (see Chapter 5). Since this is seldom practical in a dental facility, an indirect method can be used. It is recommended that the dentist obtain or make a test object (phantom) simulating the conditions of the examination. This low-cost phantom could, for example, include an extracted tooth and a small aluminum step wedge to provide a contrast scale. The phantom should be radiographed daily under fixed typical conditions (position, kVp, mA, time). The processed film should be monitored for day-to-day and long-term drifts in film density and contrast. Such changes indicate probable variation in film processing and the need for remedial action.

If such action does not resolve the problem, then the possibility exists that other factors such as the performance of the x-ray unit or the sensitivity of the film have changed. These factors can then be investigated systematically.

**The depletion of FILM PROCESSING CHEMICALS (developer and fixer) can result in unnecessarily high radiation exposures to the patient being necessary to produce a film of acceptable density.**

**If an automatic processor is used with or without automatic metering of chemicals, the amount of chemicals used must be in accordance with the instructions of the manufacturer, and must be related to the number of films processed.**

It is desirable that a regular system of replenishment or replacement be adopted, before degradation is observable in the quality control films. The system adopted will depend upon the practices in use.

If manual processing employing tanks of 2 litres or more in volume is the practice, the solutions should be replaced at least once a month and steps should be taken to minimize oxidation by the use of floating covers. A replenisher may be added to the chemistry to extend its use. A record should be kept of the dates when replenisher is added or the entire solution is replaced.

If processing containers of less than 2 litres volume are used, the chemicals should be replaced more frequently.

The development and fixing processes must take place for a measured time determined by the solution temperature and the manufacturer's time-temperature chart. This requires the use of both a thermometer and a timer. In the case of automatic processing, the time must be related to the developer temperature, either automatically or by reference to the charts. SIGHT DEVELOPMENT IS UNACCEPTABLE, since it generally implies under-developed and over-exposed film. Developer temperature should be checked periodically during each working day.

In order to maintain permanence the films must be thoroughly washed before drying. Most manufacturers recommend 20 minutes in circulating water.

It is helpful to keep track of your success with processor quality control by maintaining a log of your rejected and repeated films. A suggested method is given in Section 9.5.1.1.

### 9.5.1.1 Reject Repeat Film Analysis

Repeat films are those which necessitated another irradiation of the patient and as such, must be avoided. Reject films are those wasted films which did not require a re-exposure of the patient.

The percentage of wasted film (rejects and repeats combined) compared to the amount of film used in the facility should not exceed 3% for dental facilities.

Procedure:

1. Each operational day log the number of reject and repeat films and the reasons for using, for example, Table 9-3 below.
2. Weekly, an analysis of the reasons for rejecting or repeating films should be conducted to identify whether there is a problem in any particular area of the facility's x-ray operation. Problems identified, may include machine faults, poor processing techniques, or operator error.

**Table 9-3 Sample Reject-Repeat Film Analysis Chart**

WEEK OF____________________

| Rejects | Day 1 | Day 2 | Day 3 | Day 4 | Day 5 | Day 6 | Day 7 | TOTAL |
|---|---|---|---|---|---|---|---|---|
| -test film | | | | | | | | |
| -fogged film | | | | | | | | |
| -unused film | | | | | | | | |
| -other | | | | | | | | |
| Repeats<br>-motion | | | | | | | | |
| -too light | | | | | | | | |
| -too dark | | | | | | | | |
| -positioning | | | | | | | | |
| -artifacts | | | | | | | | |
| -other | | | | | | | | |
| Total film used<br>-total | | | | | | | | |

## 9.5.2 Exposure measurement

**Standard:**

The maximum radiation skin entrance exposure in mR per posterior bitewing radiograph is given in Table 9-1 versus the peak kilovoltage that is used.

**Equipment needed:**

- x-ray dosimeter
- method for securing dosimeter sensor during the measurement.

**Procedure:**

1. Secure the dosimeter to a flat surface.

2. Position the tube so that the cone touches the dosimeter detector and the primary beam is centred to the detector.

3. Select posterior bite-wing exposure factors.

4. Make three exposures and take the average to obtain the patient entrance exposures.

5. Compare patient entrance exposure with that in Table 9-1, Column 2, in relation to the kVp used.

6. If the measured patient entrance exposure is higher than that allowed by Table 9-1, the cause of the high exposure must be investigated and corrective action taken.

7. The exposures listed in Table 9-1 refer to "D" type film. If you are using "E" type film, the patient exposure measurement should be no greater than one-half of that listed in the Table.

### 9.5.3 Half-value layer (H.V.L.)

Standard:

The minimum acceptable half-value layer for each kVp used is given in Table 9-1.

Equipment needed:

- dosimeter
- sheets of type 1100 aluminum large enough to cover the end of cone (2 sheets 1.0 mm thick and 2 sheets 0.5 mm thick)

Procedure:

1. Secure the dosimeter to a flat surface. Position the x-ray tube with the cone tip at least 15 cm away from the dosimeter and centred to the dosimeter.

2. Select exposure factors which will give a reading of at least 100 mR at the dosimeter. These factors and the distance must remain constant throughout the test.

3. Make one exposure and record the dosimeter reading.

4. Tape 1.0 mm aluminum to the cone tip and make another exposure and dosimeter reading.

5. Continue adding aluminum to the beam until the radiation to the dosimeter has been reduced by one-half.

6. Make another exposure with no aluminum added to ensure that the unit has maintained a constant output. The output should be the same as the original exposure. If it is slightly different, average the exposures.

7. Determine the thickness of aluminum which was added to the beam that reduced the exposure to one-half the original exposure. This is the half-value layer.

Example:

| mm added Al | Exposure (mR) |
|---|---|
| 0 | 200 |
| 1 | 150 |
| 1.5 | 110 |
| 2.0 | 90 |

In this example, the amount of aluminum required to reduce the intensity by one-half is between 1.5 and 2.0 mm of aluminum. A more precise determination can be obtained by plotting measurements on semi-logarithmic graph paper as discussed in Chapter 5, Section 5.4 (see also quality control charts in the Appendix).

Compare the H.V.L. obtained with the H.V.L. required for the kilovoltage used in Table 9-1. If the HVL is too low, first the kilovoltage should be checked and adjusted if necessary. If the kVp is correct, then the service representative should be requested to add aluminum filtration until the H.V.L. requirements are met.

### 9.5.4 Beam limitation (collimation)

**Standard:**

- For intra-oral machines Section 20(1) of the Ontario X-Ray Safety Code states:

"Every dental x-ray machine shall be equipped with a beam-limiting device that limits the size of the useful beam to a maximum linear dimension of seven centimetres at the end of the localizing cone or device".

A simple test used to assess collimation and determine the alignment of the x-ray beam follows:

## Equipment needed:

- five dental films (periapical or bite-wing) or one extra-oral film

## Procedure:

1. Punch a single hole in one of the five films with a pin. Punch two holes in the second film. Continue with the remainder of the films increasing the number of holes punched by one for each film. There should be five holes in the fifth film.

2. Place the five films on the counter in a star-shaped pattern, with the corners touching (see Figure 9-1(a)).

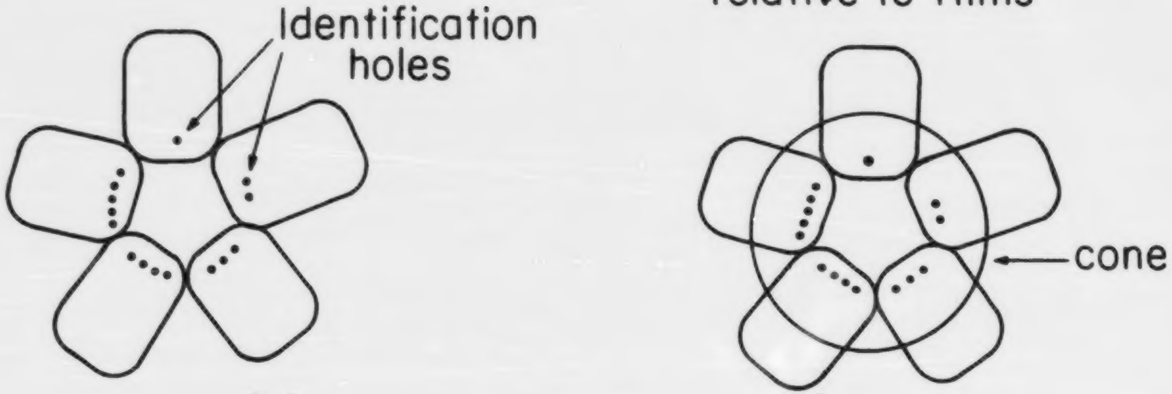
3. Centre the cone to the films, with the cone touching the films (see Figure 9-1(b)).

(a)

Placement of films

(b)

Placement of cone relative to films


Identification holes
cone

(c)

Misalignment of the collimator disc

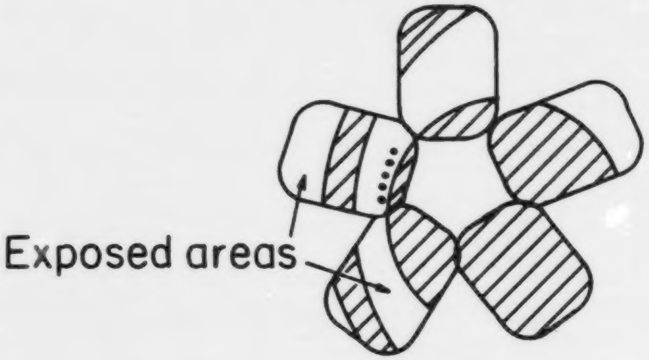

Exposed areas

**Figure 9-1 Testing Collimation and Alignment of Dental X-Ray Unit**

4. Note the position of each film (by number of holes) relative to the front, back and sides of the tubehead.

5. Expose the films using the normal bite-wing exposure setting.

6. Process the films.

7. Evaluate the films by measuring the diameter of the area exposed and by looking for any misalignment of the x-ray beam or collimation disc. Misalignment of the collimation disc will often show an extra half-moon area of primary exposure outside the main exposure area (see Figure 9-1(c)).

Beam size, alignment and character can be ascertained by exposing a large film or an array of dental films in a known pattern. The maximum field diameter at the end of the cone must not exceed 7 cm. See Section 20-(1) of the Regulations.

### 9.5.5 Further information on Quality Assurance Techniques

Further information on quality assurance techniques is provided in Chapter 5 of these Guidelines. In those situations where panoramic or cephalometric units are operated, a different approach than is described in Section 9.5 or Chapter 5 is required. Help is available in a publication entitled "Quality Assurance Program for Dental Facilities" published by the X-Ray Inspection Service of the Ontario Ministry of Health (August 1986).

## 9.6 Radiation Protection Methods

1. The prudent practitioner will provide full neck and trunk shielding during radiography, in order to reduce the radiation risk and apprehension on the part of the patient.

2. Monitor badges should be worn routinely by all personnel who take dental x rays. These are available from the Radiation Protection Bureau in Ottawa at a very reasonable annual cost. The reports issued by the Bureau are of value in keeping records regarding radiation exposure to staff. Even after consistently acceptable readings have been obtained, the practice should be continued in order to reassure staff members that the environment is a safe one in which to work.

## 10 CHIROPRACTIC X-RAY GUIDELINES

The following guidelines specifically address patient selection and equipment used for radiological examination in chiropractic facilities. Further considerations relevant to quality assurance principles and patient exposure reduction can be found in Chapters 1-7 of these Guidelines.

### 10.1 Selection Of Patients For Radiological Examination

(a) It is the policy of the chiropractic profession that radiology of the spine and related structures is an intrinsic and necessary component of chiropractic diagnosis and care. However, the Chiropractor must exercise good clinical judgement and restraint in the selection of patients for x-ray examination, based on his understanding of the predictive value of the radiological examination under various circumstances and an appreciation of the ethics involved.

(b) The radiological information sought, even if negative, must be expected to have a significant impact on the future chiropractic management of the patient, (or on evaluating previous clinical management), and the examination should be efficacious to this end. In particular, the investigative procedure must be appropriate to the patient's symptoms and to the findings upon physical examination. It is expected that the radiographic examination be capable of providing the desired information on the patient's condition relative to spinal curvatures, static and dynamic joint dysfunctions, dislocations, congenital defects and pathological changes.

(c) Previous x-ray examinations should be utilized whenever possible and may be helpful in determining the necessity of an additional or supplementary examination. This recommendation is especially important when radiography of infants and children is considered since the risks associated with ionizing radiation is thought to be higher in this group than in adults.

(d) Contra-indications for radiological examination are as follows:

(i) Pregnancy or possible pregnancy. There are few conditions that warrant the use of spinal irradiation during the early months of pregnancy. (For further discussion on the radiography of pregnant women please see Chapter 8, Section 8.5).

(ii) Spinal radiography is not usually justified in infants and small children, since the risk associated with ionizing radiation is much higher in this group than in adults, while the potential benefit is reduced because of the juvenile appearance of the ossification of centres in the spine.

(iii) Radiology is not recommended when the patient's body type and/or size precludes good radiographic resolution, or when the physical state of the patient does not permit proper immobilization or positioning.

## 10.2 Selection Of Equipment

The following recommendations apply to equipment and image receptors used in chiropractic radiology:

(a) The x-ray generator should be capable of producing at least 300 mA at 125 kVp, with full-wave rectification.

(b) A rotating-anode tube is required.

(c) A fixed in-beam filter should provide a minimum of 2.5 mm Al equivalent total filtration (including inherent filtration). However, the recommended total filtration is 3-4 mm (Note: reference here is to total filtration, not HVL).

(d) A grid is essential for good radiographic quality in imaging the spine and related structures. The bucky should have a minimum grid ratio of 8:1 and a maximum ratio of 12:1 with a minimum of 60 lines to the inch. If preferred, a stationary fine-line grid may be used instead of a moving (potter-bucky) grid.

(e) A properly centred square-leaf collimator, equipped with a light beam localizer, is essential for chiropractic radiology.

(f) A film-screen combination, with either a high-speed or an ultra high-speed, i.e. rare-earth, intensifying screen should be used. (See Chapter 3, Section 3.6.) Non-screen films should not be used since the small increase in resolution obtained with these films does not justify the required large increase in patient exposure.

## 10.3 Good Radiographic Practice

The requirements for good radiographic practice in chiropractic imaging are similar to those for general medical radiology, but the following points are worth emphasizing with respect to radiology of the spine and related structures:

(a) The routine use of oblique projections in lumbar spine radiography is not justified. These projections should be used only when the antero-posterior and lateral views suggest further investigation.

(b) Comparative radiographs of the injured and uninjured limb should not be done routinely. When comparative x-rays are necessary, the minimum number of views should be taken.

(c) The focus-film distance should be at least 72 inches and preferably 84 inches for full spine radiography. For sectional radiography the longest FFD compatible with the grid should be used.

(d) An in-beam compensating filter (or filters) should be used in full spine radiography to reduce the amount of radiation received by the thinner body parts and to equalize the density across the film. Graduated or split screens must not be used.

(e) The highest kVp consistent with good image quality and minimum patient exposure should be employed.

(f) Gonad shields should be employed when radiographing children and adults of reproductive capacity, whenever such shielding is possible and does not interfere with the area under study.

(g) Radiosensitive tissues such as the breasts and thyroid should be shielded by the appropriate appliance whenever possible, so long as it does not hinder diagnosis.

(h) All foreign objects (e.g. hairpins, earrings, false teeth) which might produce unacceptable artifacts should be removed before the exposure is made.

(i) As in all radiographic examinations, proper patient positioning is essential in imaging of the spine and related structures.

(j) When conducting upright studies, the patient should be immobilized.

(k) Careful and appropriate beam collimation is particularly important in spinal studies in which the field area can be exceptionally large. The primary beam should exclude the eyes, sensitive organs such as the thyroid and gonads, and as much of the bone marrow as possible. In particular, the field should be no wider than is essential for the study: ideally, no wider than the mamillary line and the lateral margins of the acetabula. In any case, the x-ray beam must always be smaller than the film used. The reduction of field size is important both from the point of view of the radiation exposure of the patient and the attainment of good image quality (reduction of scattered radiation).

(m) Proper film-processing procedures, as discussed in Section 3.7, should always be followed. Sight processing should never be used.

## 10.4 Quality Assurance Program

A programme of radiological Q.A. in a chiropractic facility is no different from that in a general medical radiology facility of comparable size, and may be readily carried out, in-house, by the chiropractor or by technical staff using the appropriate test equipment. Alternatively, except for daily photographic quality control, the Q.A. program could be carried out by a consultant group or a mail-in service if available. The minimum requirements for a Quality Assurance program are listed in Table 10-1 below, and suggested techniques for conducting the required tests are found in Chapter 5.

It is emphasized that these sections relate to the minimum requirements and for an in-depth understanding of the rationale of quality assurance in x-ray diagnosis, the reader is advised to become familiar with Chapters 1-7 of these Guidelines and selected publications listed in Chapter 12.

## Table 10-1 Quality Assurance Procedures In Chiropractic X-ray Facilities

| Test or Procedure | Frequency | Section in Guidelines |
|---|---|---|
| Photographic quality control | Every operational day | 5.1 |
| Patient entrance exposure measurements | Every six months and upon alteration or servicing of the machine | 5.2 |
| Collimation | " | 5.3 |
| Half-value layer | " | 5.4 |
| Phototiming parameters including operation of back-up timer | Every six months | 5.8, 5.9 |

# 11 CHIROPODY (PODIATRY) GUIDELINES

X-ray evaluation of the foot and related structures is essential if the chiropodist (podiatrist) is to determine a diagnosis and/or confirm a clinical diagnosis. Of particular importance to the chiropodist (podiatrist) are x rays taken to determine biomechanical function and these investigations entail weight-bearing views utilizing specialized techniques and interpretation.

For the protection of the patient, the ALARA principle (as low as reasonably achievable) should be applied to all chiropody (podiatric) radiology. The objective should always be to obtain the optimum diagnostic benefit consistent with the lowest practical radiation dose, and hence the least risk, to the patient.

## 11.1 Selection of Patients

The need for radiological assessment of the patient must always be justified. The potential value of the information likely to be obtained from the radiograph must be weighed against the possible hazards of the examination. To expose the patient to radiation without a prior history and a clinical examination is ethically unacceptable.

## 11.2 Radiation Risks

Both the radiation dose to the individual patient and the overall dose to the Ontario population from chiropody (podiatric) radiography are relatively small - much smaller than the contributions from medical, dental and chiropractic radiography. The reasons for this are as follows:

(i) Relatively few chiropody (podiatric) x-ray examinations are performed;

(ii) A chiropody (podiatric) examination involves only a few films per patient;

(iii) Since the foot attenuates x rays only to a small extent, a relatively low entrance exposure suffices to produce a useful image; and,

(iv) The irradiated tissues of the foot are relatively insensitive to radiation, as compared with (for example) the thyroid in dental radiography or the breast and bone marrow in medical radiography.

Nevertheless the ALARA principle requires exposures to be reduced to the minimum level consistent with a satisfactory diagnostic image. This can be achieved by proper attention to good radiographic practice, including collimation of the primary beam, shielding of sensitive tissue subject to scattered radiation (such as the gonads), choice of appropriate exposure factors and film/screen combination, and elimination of leakage from the x-ray tube housing.

## 11.3 Contraindications

An x-ray examination of a pregnant or possibly pregnant patient should be undertaken only when it is deemed to be clinically essential. Adequate shielding of the abdomen and pelvis during the exposure are essential.

## 11.4 Selection Of Equipment

Chiropody (podiatric) x-ray equipment usually remains in service for many years and should be chosen with care. Chiropody (podiatric) x-ray studies frequently require weight bearing views and it is therefore necessary to select equipment which has either been designed, or can easily be modified, for such views.

### 11.4.1 X-ray unit

(i) The unit should either incorporate an orthoposer or be employed in such a way that a separate orthoposer may be utilized.

(ii) Free movement and angulation of the tube head into a variety of positions, plus ready fixation of the head in these positions, are essential. The commonly required views of the foot are dorso-plantar, lateral and oblique.

(iii) The unit should be capable of producing x rays of at least 70 kVp with a tube current of at least 10 mA. Kilovoltage should be variable, with at least three settings. The total filtration should be at least 1.5 mm of aluminum and the half-value layer at least 1.5 mm Al at 70 kVp and 2.1 mm Al at 71-79 kVp (see Table 8 of the Regulation).

(iv) An electronic timer is preferable to a mechanical timer.

### 11.4.2 Film

The maximum entrance exposure listed in Table 6 of the Regulation is 200 mR. This value applies to a dorso-plantar view taken with "direct film", i.e. a non-screen film intended for use without an intensifying screen. However, a tenfold reduction in exposure is easily obtained by the use of an appropriate film-screen combination in a cassette. Many such combinations are available which produce radiographs of good diagnostic quality and permit entrance exposures of as little as 10 mR for a dorso-plantar view. The ALARA principle points to the use of a film-screen cassette rather than a direct film.

### 11.4.3 Collimation

Only the part of the patient to be studied should be exposed to radiation. This principle requires the use of a collimator with a light beam localizer. In some cases the beam can be limited to only a portion of the foot. Examples of this are the pre-and post-operative views in arthoplasty (head resection) of a toe, and osteotomy or ostectomy of a metatarsal.

Additional information on the selection of equipment for radiographic imaging is provided in Chapter 3, Section 3.1.

## 11.5 Protective Methods

(i) Pelvic shields should be used routinely and, in particular, for women of child-bearing age.

(ii) A shield should be placed behind the cassette when a lateral view is taken, so as to avoid irradiating the foot not being studied.

(iii) The chiropodist (podiatrist) and all clinical staff should routinely wear personnel radiation monitors (TLD badges), available from the Radiation Protection Bureau in Ottawa. The monitor should be carried at waist or chest level, under the lead apron if worn.

## 11.6 Radiographic Technique

Since biomechanical views are important for functional assessment, standard techniques should be established and followed in order to ensure optimum diagnostic quality and to facilitate comparison from one study to another.

(i) Distance should be kept constant for each view. Differences in patient dimensions should be allowed for by varying the milliampere-(mAs) and kilovoltage (kVp).

(ii) Antero-posterior (dorso-plantar) and lateral views should be taken at the angle and base of stance.

(iii) Lateral views should be taken at 90° to the sagittal plane.

(iv) Antero-posterior (dorso-plantar) views should be taken at 90° to the dorsum of the foot and in the sagittal plane.

(v) The highest kVp which still provides acceptable images should be used.

## 11.7 Quality Assurance Programme

The purpose of a quality assurance (QA) programme is to ensure proper and consistent performance of equipment and compliance with the Regulation with respect to beam quality and patient entrance exposure. The types and frequencies of the QA tests legally required in a chiropody (podiatric) facility are set out in Table 4 of the Regulation and this list is reproduced below for convenience.

Table 11-1 Quality Assurance Procedures In Chiropodic (Podiatric) X-ray Facilities

| Test or Procedure | Frequency | Section in Guidelines |
|---|---|---|
| Photographic quality control | Every operational day | 5.1 |
| Patient entrance exposure measurements | Every 24 months and upon alteration or servicing of the machine | 5.2 |
| Collimation | Every 12 months and upon alteration or servicing of the machine | 5.3 |
| Half-value layer | Every 12 months and upon alteration or servicing of the machine | 5.4 |

Alternative techniques for carrying out the various tests are set out in Chapter 5 of these Guidelines, to which the reader is referred for details. The important concepts, as they affect a chiropody (podiatric) facility, are discussed below.

### 11.7.1 Photographic quality control tests

The purpose of these tests is to monitor the quality and consistency of photographic processing, since the chemical composition of the developer and the time and temperature of processing all have a profound influence on the quality of the radiograph. Three alternative tests are described in section 5.1.4, the preferred method being "sensitometry and densitometry". However, the simplest method for most chiropody (podiatric) facilities makes use of a standard test object or phantom such as an aluminum step wedge made of a number of thicknesses of aluminum. Using standard technique factors (kVp, mA, exposure time, distance), as in Section 11.6 (i) above, the test object is radiographed every operational day and the film is developed under standard conditions of time and temperature. The resulting image is then compared with previous films or preferably with a calibrated gray scale. If a change in the appearance (density, contrast) of the radiograph of the test object is observed, then more refined tests must be carried out to determine the reason for the change, i.e. whether the change originates in the x-ray source, the screen/film combination or the processor. (See Sections 5.1.4., 5.1.5 and 5.1.6 for further information.)

### 11.7.2 Entrance exposure measurements

The entrance exposure for a patient of average size is an important index of the successful application of the ALARA principle: the dose received by the patient should be as low as reasonably achievable, consistent with good radiographic quality.

Measurement procedures are described in section 5.2. Briefly, a small dosimeter is set up in the x-ray beam and an exposure (or, better, a series of 3 or 4 exposures with successive dosimeter readings) is made under conditions (kVp, mA, exposure time, distance) identical with those used for a standard clinical view such as dorso-plantar. The simplest procedure is to place the dosimeter on a block of plastic (e.g. lucite) 8 cm thick resting on the table, with the beam pointing vertically downwards, i.e. distance between x-ray focus and dosimeter is 92 cm. Instead of a plastic block, a bucket of water may be used if arrangements can be made to support the dosimeter on the surface. For a field of small dimensions the measured dose includes a component of about 20% due to backscatter and this contribution has to be removed by multiplying the measured value by the appropriate factor (about 0.85) in Table 5 - 3 of these Guidelines.

With regard to the dosimeters needed for this test, there are several possibilities:

(i) Mailed packets

A number of commercial agencies provide sealed packets containing film or thermoluminescent dosimeters (TLDs). The chiropodist (podiatrist) exposes the packet as indicated above, and then returns the packet to the agency, where TLD is processed and the entrance exposure determined from calibration charts applicable to the radiation used.

(ii) Agency measurements

Some agencies will make the required measurements in the chiropodist's (podiatrist's) office using calibrated dosimeters.

(iii) In-house measurements

A chiropodist (podiatrist) wishing to carry out the measurement himself can do so by using a "pocket personnel dosimeter" which is a small ionization chamber resembling a pen. The dosimeter is first charged, using the accompanying charger, is then exposed as described above, and finally is "read out" on the charging/reading device.

### 11.7.3 Collimation

The purpose of this test is to ensure that the x-ray field delineated by the collimator corresponds both in position and dimensions with the field indicated by the light beam localizer. This test is particularly important in chiropody (podiatric) radiography since the field is often quite small and an error in localization could result in an unsatisfactory or unacceptable radiograph. Details of the test are given in section 5.3.

### 11.7.4 Half-value layer

The half-value layer (H.V.L.) of the beam is an index of the penetrating power of the radiation and this affects both the patient dose and the image contrast. Minimum values of H.V.L., as a function of the operating kilovoltage, are given in Table 8 of the Regulation. The measurement procedure is described in section 5.4. This measurement can be carried out at the same time as the patient entrance exposure (although H.V.L. has to be measured more frequently: every 12 months). In principle the three alternative dosimeters mentioned above for exposure measurements (section 11.7.2) can also be used for the H.V.L. measurement. However, the procedure is more complicated than for the exposure measurement previously described, and a chiropodist (podiatrist) who is uncomfortable with the procedure is advised to utilize the services of an external agency.

## 11.8 Referral of Patients

When a chiropodist (podiatrist) refers a patient to another practitioner (chiropractor, physician or podiatrist), or to a medical x-ray facility, the relevant radiographs and/or a report should always be forwarded to the consultant or should accompany the patient.

## Summary

The responsibility lies with the individual chiropodist (podiatrist) to realize the optimum diagnostic benefit to the patient with the minimum radiation exposure. The guidelines presented in this chapter are intended to help the chiropodist (podiatrist) to achieve these goals and thus to comply with both the Regulation and the ALARA principle.

# 12 REFERENCES

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(Additional references accompany Appendix)

# APPENDIX: QUALITY CONTROL FORMS AND CHARTS

The Regulations require that records be maintained of the procedures and tests carried out in the quality assurance program. The data collected in the quality assurance program are more useful if they are maintained in a form which is easily read and allows the review of each measurement to be made over the history of the equipment. Many simplified methods of measurement and data collection for quality assurance in diagnostic radiology have been described (1-9). The charts on the accompanying pages are intended to illustrate the type of record keeping appropriate for a quality assurance program. The list is by no means intended to be all-inclusive, but covers some of the more commonly performed QA tests (referred to in Chapter 5) including most of those required by the Regulations. It is expected that each institution will develop a method of record keeping to suit its particular need, in keeping with the requirements of the Regulations as well as the size and patient load of the facility.

## Chart 1: Room equipment survey

Details of the equipment in each room should be maintained for review and to meet legislative requirements. Records should be kept of all service carried out on the equipment since installation.

## Chart 2: Photographic quality control

Photographic quality control must be carried out each operational day as indicated in Chapter 5. At approximately the same time each operational day, a sample of x-ray film should be exposed to a sensitometer and processed. Measurements of contrast index (density difference of 2 steps on the straight line portion of the characteristic curve), speed point and base plus fog should be recorded. Other data related to the processor, such as developer temperature, developer replenisher rate, fixer replenisher rate and cycle time can also be recorded on the same chart.

### Chart 3: Patient entrance exposure measurements

The patient entrance exposure for a number of standard views for an average patient can be determined in a number of different ways as indicated in Chapter 5. Column 7 of chart 3 allows a comparison of these exposures with the acceptable range of values for a given view. The upper limits of the range for each view are the maximum entrance exposure values as specified in the Regulations.

### Chart 4: Collimation

### Chart 5: Half value layer determination

The half value layer (HVL) of the x-ray beam must be measured every six months for chiropractic and medical facilities and every 12 months for dental and podiatric facilities. Methods for measuring the HVL of an x-ray beam are described in Chapter 5. The experimental procedure used and the measurements taken should be recorded as suggested in Chart 1 and the data plotted in a form as shown in chart 2a to obtain the HVL at a nominal kVp. This HVL value should then be compared to the requirements of the regulations. HVL values for a given kVp should be recorded as a function of time as suggested by chart 2b. Other quality assurance parameters should also be recorded as a function of time using a form similar to that of chart 2b.

## Chart 6: Fluoroscopy patient entrance exposure measurement

The patient entrance exposure measurements for fluoroscopy can be determined as described in Chapter 4. The resolution as well as other tests of the fluoroscopy system should also be measured periodically using an appropriate method (9, 4, 5) and recorded.

## Chapter 7: Timer accuracy

## Chart 8: mA linearity

The mA linearity should be checked at a number of different kVp values covering the range of use of the equipment. Values of relative exposure as a function of mR/mAs for each mA station can be tabulated as shown in chart 8. Data can also be displayed graphically by plotting mR/mAs as a function of mA or mAs as shown in chart 8a. A linear system will yield a horizontal line on this graph.

## Chart 9: kVp Accuracy

The actual kVp at a nominal value of 80 kVp, or an alternative kVp value if more appropriate, should be determined for all the mA stations routinely used. The actual kVp for a number of other kVp settings should also be measured for one of these mA stations. Methods for kVp determination are described in Chapter 5.

## Chart 10: Radiation Output Exposure

Measurement of mR/mAs as a function of kVp at a fixed distance from the focal spot of the x-ray tube is of value in determining the stability of tube output with time and also in the calculation of patient entrance exposure values for a standard patient as described in Chapter 4.

## Chart 11: Reject/repeat analysis

Forms, such as that shown in chart 11 should be used for analysing retakes on both a departmental and individual level (7, 9).

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## Chart 1a: Room equipment survey

Hospital and Room number : ____________________ Date : ______________

### X-RAY GENERATOR:

Manufacturer ____________________
Model ____________________
Serial # ____________________
Date purchased ____________________
Fixed ________ Mobile ____________
CD ___ Battery ___ 110 ___ 220 ___
Single phase _____ Three phase _____
High frequency ____________________
Maximum kVp _______ Maximum mA _____

### OVERHEAD:

Manufacturer ____________________
Date purchased ____________________
Model ____________________

### COLLIMATOR:

Manufacturer ____________________
Model ____________________
Serial # ____________________
Date purchased ____________________
Source-to-image distance __________ cm
Source-to-tabletop " ____________ cm
(fluoro)

### GRID:

Manufacturer ____________________
Date purchased ____________________
Grid ratio ____________________
Lines per inch ____________________
Focus __________ to ____________ cm
Interspace material ______________
Stationary: yes __________ no __________

### SKULL UNITS:

Manufacturer ____________________
Model ____________________
Date purchased ____________________

### TOMOGRAPHIC UNITS:

Manufacturer ____________________
Model ____________________
Serial # ____________________
Date purchased ____________________
Linear ________ Circular ________
Oval ________ Tri-spiral ________
Hypocycloidal ____________________

### FILM CHANGERS:

Manufacturer ____________________
Serial # ____________________
Date purchased ____________________
Model ________ Film size ________
Cut film ______ Roll film ________

### USAGE:

Maximum kVp used ______________
Maximum time used ______________
Number of exams per week _______
Number of films per week _______
Maximum mA used ______________
Maximum mAs used ______________

### MISCELLANEOUS/COMMENTS:

Chart 1b: Room equipment survey

Hospital and Room Number: ______________________________ Date: ____________________

X-RAY TUBES:

Manufacturer ____________________

Model ____________________

Serial # ____________________

Date installed ____________________

Date removed ____________________

Fixed __________ Mobile __________

Focal spot sizes (mm) __________

Radiographic __________ Fluoro __________

Grid pulse ______ High speed ________

Bias focus ____________________

Horns: 0° _______ 90° ______ 135° ____

180° _______ 270° __________

Chart 1c: Room equipment survey

Hospital and Room Number: ____________________ Date: ________________

## FLUOROSCOPIC SYSTEM:

### IMAGE INTENSIFIER:

Manufacturer ____________________ Fixed ________ Mobile __________

Model __________________________ ZnCdS ________ CsI __________

Serial # ________________________ Size-Input ______________ (cm)

Date purchased __________________ Output ______________ (cm)

Conversion factor ______________

### TV CAMERA:

Manufacturer ____________________ Fixed ________ Mobile __________

Model __________________________ Plumbicon ______ Vidicon __________

Serial # ________________________ Other (Specify) ______________

Date purchased __________________ 525 ____ Other (Specify) ________

### TV MONITOR:

Manufacturer __________________ Fixed ________ Mobile ________

Model __________________________ Size __________

Serial # ________________________ Date Purchased ________________

### SYSTEM LIMITING RESOLUTION:

| Field Size | mA | kVp | lp/mm |
|---|---|---|---|
| | | | |
| | | | |
| | | | |

### MISCELLANEOUS/COMMENTS:

Chart 2: Photographic quality control

Hospital: ____________________ Processor #:_______________ Location:_______________

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **DATE**, Year______ | Month | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Day | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Time | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | S | M | T | W | T | F | S | S | M | S | M | T | W | T | F | S | S | W | S | M | T | W | T | F | S | S | F | S | M | T | W | T | F | S | M | T | W | T | F | S | S |
| | | +.25 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **SPEED** | | .20 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Upper Limit | +.15 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | .10 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | .05 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Normal Density:____OD | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | .05 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | .10 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Lower Limit | -.15 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| (Step_____) | | .20 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | +.25 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **CONTRAST** | | .20 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Upper Limit | +.15 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| (density difference) | | .10 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | .05 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Normal:_____OD | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | .05 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | .10 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Lower Limit | -.15 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| (Step____ minus step____) | | .20 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **BASE** | | +.04 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| + | | .02 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **FOG** | Normal:_____OD | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Developer Temperature (°C) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Developer Replenisher, cc | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Fixer Replenisher Rate, cc | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Cycle Time, Seconds | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Comments - Chem changed | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

Chart 3: Patient Entrance Exposure Measures (for acceptable film density)

Hospital and Room Number: ____________________________________________

Date: ________________

X-ray tube: ___________

| Projection | Patient thickness (cm) | F. F. D. (cm) | Kvp | mAs | Patient entrance exposure (mR)* | Acceptable Range of patient entrance exposure (mR) |
|---|---|---|---|---|---|---|
| Skull Lateral | 15 | | | | | 35-170 |
| Cervical Spine A-P | 13 | | | | | 25-120 |
| Thoracic Spine A-P | 23 | | | | | 80-400 |
| Chest PA | 23 | | | | | 4-20 |
| Lumbar Spine A-P | 32 | | | | | 100-500 |
| Abdomen A-P | 23 | | | | | 90-450 |
| IVP | 23 | | | | | 100-500 |
| Full Spine | 23 | | | | | 50-250 |
| Foot (Dorso-Plantar) | 8 | | | | | 40-200 |
| Mammography (without grid) | (film/ screen) 4 | | | | | **150-500 |

* Exposures measured in air without backscatter.

** Low end of exposure range with special double-screen system

## Chart 4: Collimation

Hospital and Room Number: ______________________________

Date: ________________________

X-ray tube: ________________________

SID: ________________________

Focal spot: ________________________

Nominal kVp: ________________________

mAs: ________________________

Time: ________________________

| Date | Deviation (mm) | | | | Centre Alignment (% of SID) | Automatic Field Size | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Left | Right | Top | Bottom | | 8 x 10 | 10 x 12 | 11 x 14 | 14 x 17 |
| | | | | | | | | | |
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## Chart 5: HVL Determination

Hospital and Room Number: ______________________________

Date: ________________________

X-ray tube: __________________

Added filtration: __________________________

Focal spot: ____________________

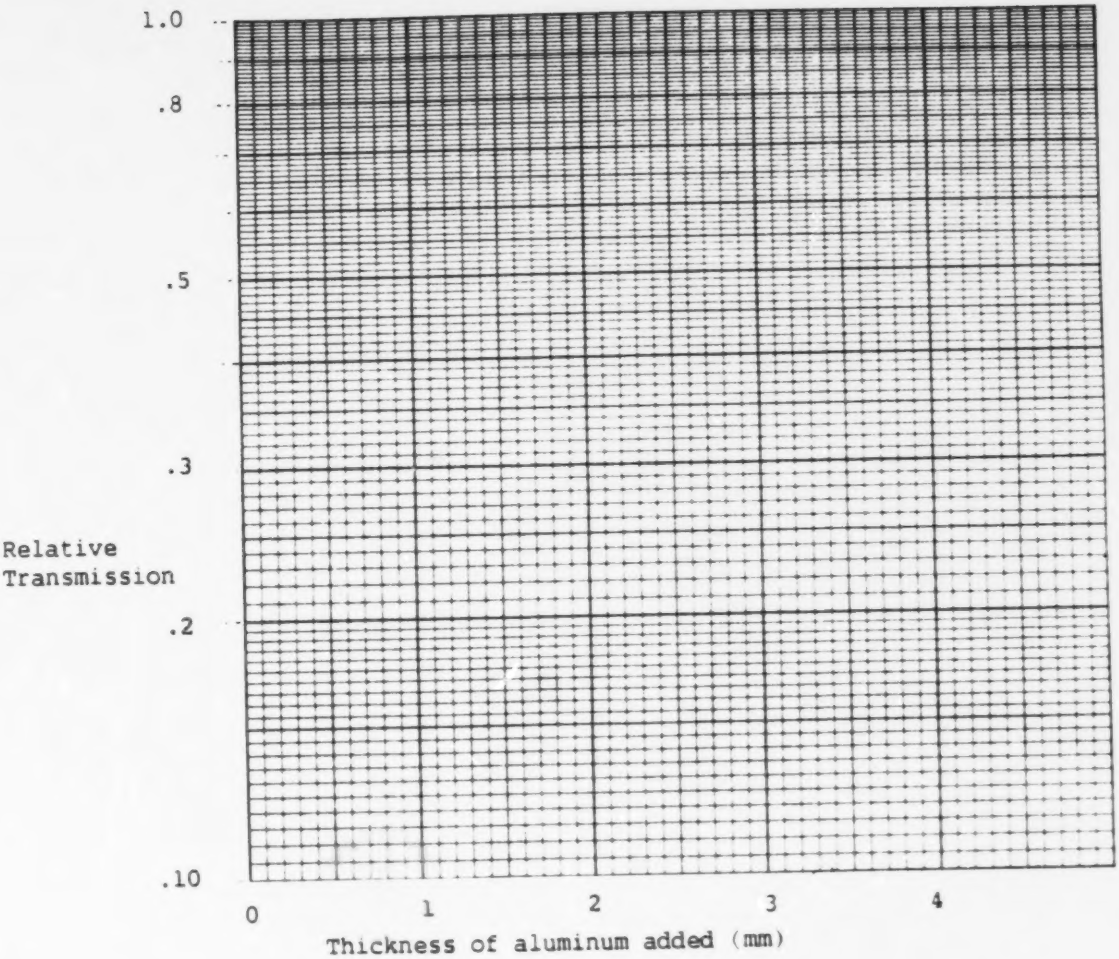
Nominal kVp: ___________________

mAs: ____________________

Time: ____________________

| Thickness of aluminum (mm) | Dosimeter reading | Relative Transmission |
|---|---|---|
| 0 | | |
| 0 | | |
| 0 | | |
| 0 (average of above 3) | | 1.00 |
| 1 | | |
| 2 | | |
| 3 | | |
| 4 | | |
| 5 | | |
| | | |

Chart 5a: HVL Determination



kVp nominal: ___________

kVp actual: ___________

HVL: ___________

## Chart 5b: HVL Determination

Hospital and Room Number: ______________________________

X-ray tube: ______________________________

Added filtration: ______________________________

Focal spot: ______________________________

Nominal kVp: ______________________________

mAs: ______________________________

Time: ______________________________

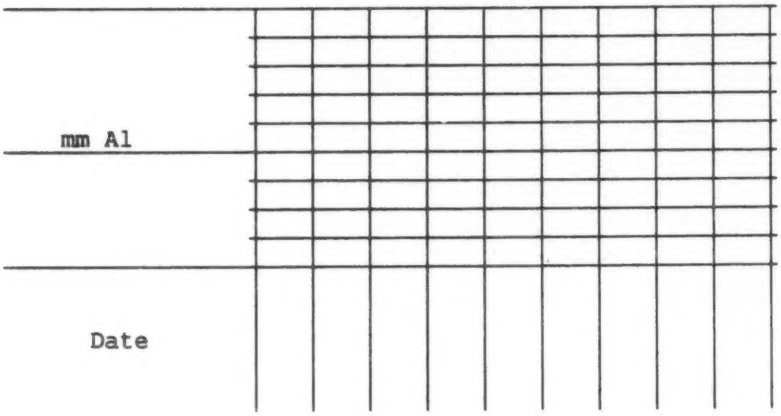


Chart 6: Fluoroscopy patient entrance exposure measurement

Hospital and Room Number: ______________________________

Date: ______________________

X-ray tube: make _____________ model _____________ age _____________

Filtration: inherent _________ collimator _______ added _______ total ___________

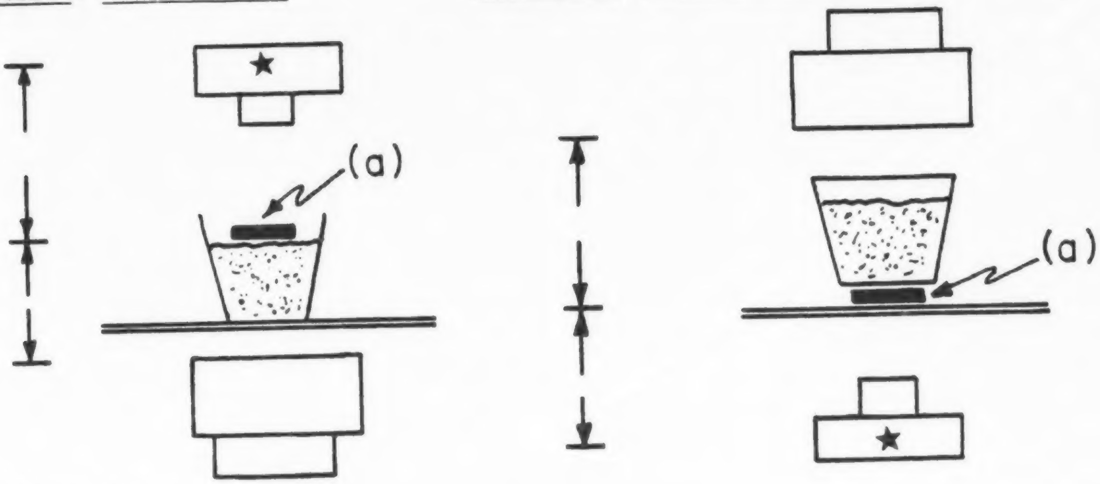
Focal spot: ________________

Generator: make __________ model __________ age __________ waveform ___________

Imaging system: make __________ model _________ age _________ phosphor __________

Grid: in/out ________________ grid ratio _____________ lines _______________

Overtable: ____________ Undertable: _____________



(a) Dosimeter

| | Phantom | Nominal kVp | Nominal mA | Reading | R/min |
|---|---|---|---|---|---|
| Manual | 20 cm water | | | | |
| | | | | | |
| | | | | | |
| Auto | 20 cm water | | | | |
| | | | | | |
| | | | | | |
| Maximum | 3 mm lead | | | | |

## Chart 7: Timer accuracy

Hospital and Room Number: ______________________________

Date: ______________________

X-ray tube: ______________________________

Generator: make ____________ model ___________ age ________ waveform _________

Nominal kVp: ___________________

Nominal mA: ____________________

Focal Spot/detector distance: _____________

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Nominal Time | | | | | | | | |
| Actual time/# pulses | | | | | | | | |
| Nominal time | | | | | | | | |
| Actual time/# pulses | | | | | | | | |
| Nominal time | | | | | | | | |
| Actual time/# pulses | | | | | | | | |

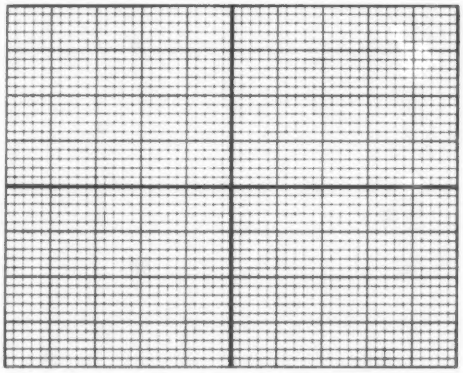
### Waveform Analysis

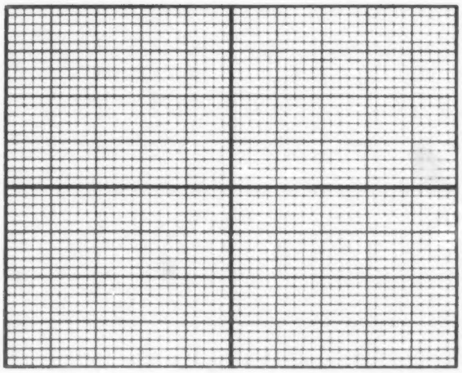
Generator settings:

kVp _______ mA ______ time _______ kVp ______ mA _______ time ______

Oscilloscope settings:

time base _________ vertical scale _________ time base _______ vertical scale _______





## Chart 8: mA linearity

Hospital and Room Number: ______________________________

Date: ______________________

X-ray tube: __________________

Generator: make __________ model __________ age __________ waveform ____________

Focal spot/detector distance: _____________

| kVp: time: | | | kVp: time: | | | kVp: time: | | |
|---|---|---|---|---|---|---|---|---|
| Nominal mA | Exposure mR | mR/mAs | Nominal mA | Exposure mR | mR/mAs | Nominal mA | Exposure mR | mR/mAs |
| | | | | | | | | |
| | | | | | | | | |
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Chart 8a: mA linearity

Hospital and Room Number: ______________________________

Date: __________________________

X-ray tube: ____________________

Generator: make __________ model __________ age _________ waveform _____________

Focal spot/detector distance: ______________

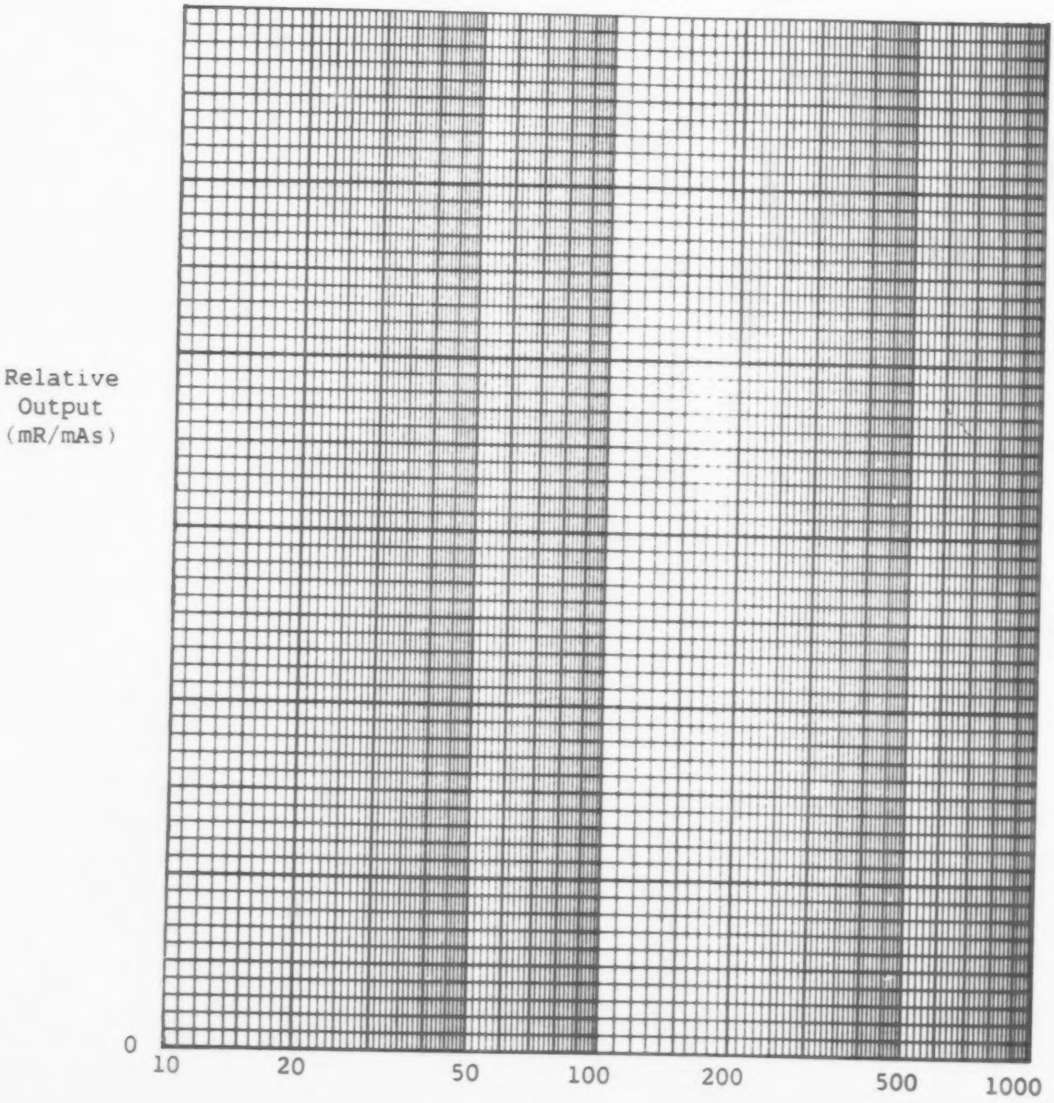

Chart 9: kVp

Hospital and Room Number: ______________________________

Date: ______________________

X-ray tube: __________________

Generator: make__________model__________age_________waveform_____________

Focal spot/detector distance: _____________

| Nominal kVp | mA | Reading | Measured kVp |
|---|---|---|---|
| 50 | | | |
| 60 | | | |
| 70 | | | |
| 80 | | | |
| 90 | | | |
| 100 | | | |
| 110 | | | |
| 120 | | | |

Chart 10: Radiation output exposure

Hospital and Room Number: ______________________________

Date: ________________________

Generator: ____________________

X-ray tube: ___________________

Filtration: ___________________

Focal spot/detector distance: ______________

| kVp | mA | Time | Exposure* at 100 cm | mR/mAs at 100 cm |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
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| | | | | |

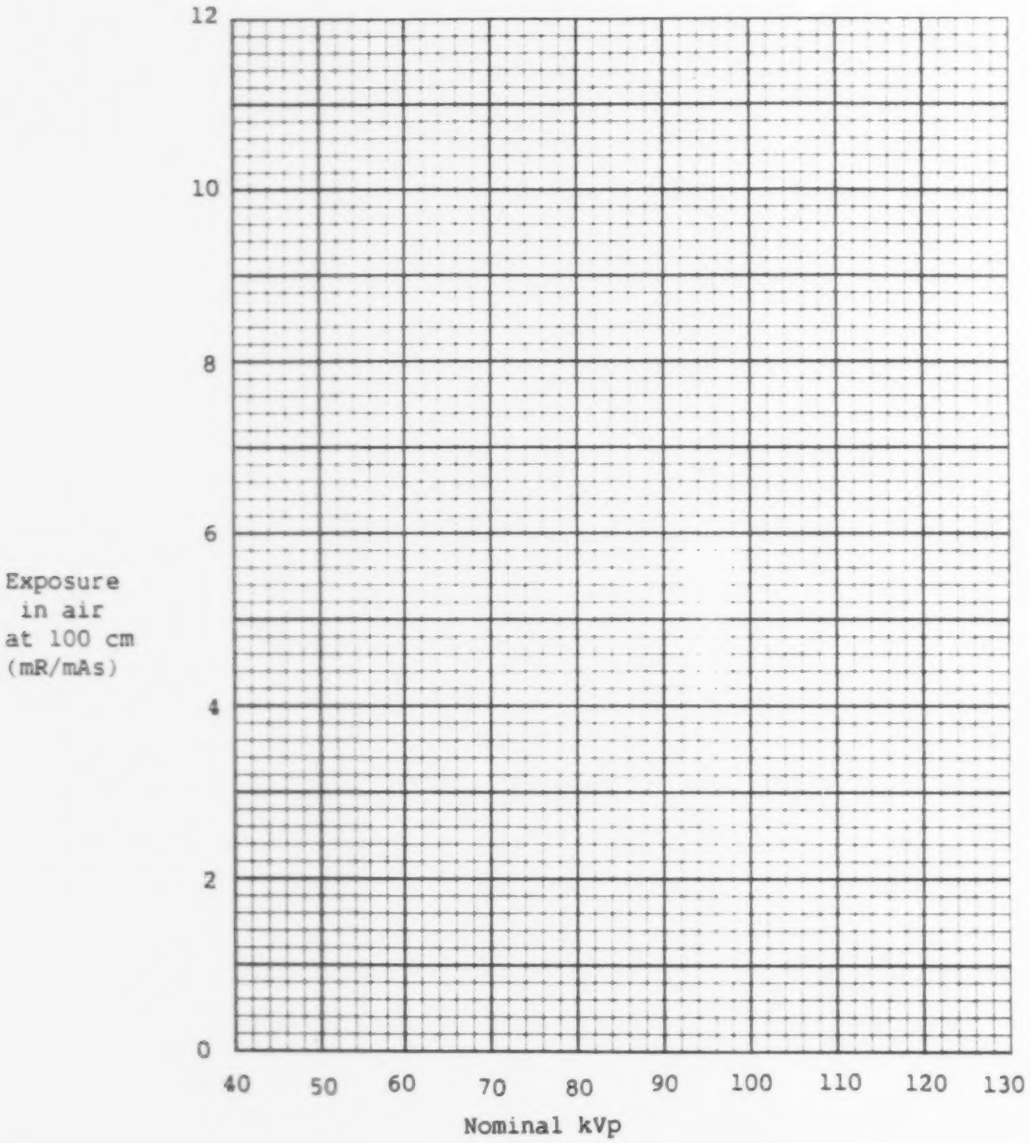
*Output exposure in mR at 100 cm focus/chamber distance without scatter

## Chart 11: Radiation output exposure

Hospital and Room Number: ______________________________

Date: _________________________

Filtration:



## Chart 12: Reject/repeat analysis

Hospital and Room Number: ______________________

Date: From ______________ to ________________

| Cause | Number of Films | Percentage of Rejects | Percentage of Repeats |
|---|---|---|---|
| 1. Positioning | | | |
| 2. Patient Motion | | | |
| 3. Light Films | | | |
| 4. Dark Films | | | |
| 5. Clear Film | | ☒ | ☒ |
| 6. Black Film | | | |
| 7. Tomo Scouts | | | ☒ |
| 8. Static | | | |
| 9. Fog-Darkroom | | | |
| 10. Fog-Cassettes | | | |
| 11. Mechanical | | | |
| 12. Q.C. | | ☒ | ☒ |
| 13. Miscellaneous (?) | | | ☒ |
| 14. Good Films | | | |
| Total Waste (1-14) %| | | ☒ | ☒ |
| Total Rejects (All except 5 and 12) | | | ☒ |
| Total Repeats (1-4, 6, 8-11, 14) | | ☒ | |

Total Film Used ☐